eHealth Standards and Profiles in Action for Europe and Beyond

eStandards Roadmap for collaborative & sustainable standards development
Recommendations for a globally competitive Europe

Extended Summary
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Shared Services of the Ministry of Health, Portugal.
Dedicated to
Henk E. Bakker (1959-2015)
Personal Health Record Ambassador

Marcel Heldoorn of the Dutch Patient Federation, who accepted the dedication on behalf of the family of Henk Bakker said: “Patients become digital citizens faster than hospitals are embracing digital transformation. The patient perspective is a formidable and indispensable driver of change in the digital age, when connected in a safe and meaningful way to the health and wellness professionals. The Patients federation of the Netherlands has taken the initiative for a personal digital health environment for which Henk Bakker was one of the early ambassadors. We still share Henk’s experiences and ideas to convince people of the importance of digital health tools for patients almost every day. Making a personal health environment meaningful for patients requires standards for information exchange and a clear regulatory framework to drive trust and adoption. Most standards and regulatory frameworks are the result of co-creation with all parties concerned including patients, health professionals, healthcare providers, their organisations, and the health IT industry. In our shared vision, the connected personal health environment serves as a solid foundation for all kinds of innovative applications ranging from health management for chronic conditions to research into treatment of rare diseases and complex and ill understood conditions. The availability of extensive patient data fuels innovation. Putting patients in charge of what can and cannot be done with their personal health data is key to instilling trust in these innovations. I want to underline and recognise the dedication of your roadmap to Henk Bakker, as one of the ambassadors of the Patient Federation for personal health record adoption.”
Henk Bakker’s Story

Henk describes his autoimmune disease, sarcoidosis\(^1\), as “an overreaction, a lung condition caused by infections that create scar tissue causing problems with the flow of oxygen in my lungs.” Living with sarcoidosis, Henk discovered the value of taking control of his life by registering and monitoring his health. According to Henk, it was great help to get a better understanding of what is going on and which aspects of the disease he could understand, influence, and control. Henk started using a Personal Health Record (PHR) because he dealt with several healthcare professionals, lung specialists, cardiologist, physical therapist, General Practitioner (GP), pharmacist, etc. Each of them captured only parts of his health information. Only Henk could have the full picture. Henk needed an overview and started using PatientsLikeMe, one of several PHRs and patient networking tools freely available on the Internet. Even though the particular PHR offers a range of functions, Henk uses the PatientsLikeMe PHR primarily to store test results and personal measurements. This way, Henk gets insights into his current health situation and how it develops over time. To Henk’s regret, the only data in his PHR is data that he entered or uploaded himself after actively requesting this information from his healthcare providers. The data in his PHR supports Henk during his regular consultations with health professionals. Henk can authorise professionals to access his PHR. This way he can actually assemble his own care team and this is something care providers really have to get used to. The only person that routinely accesses Henk’s PHR is his GP, who actually checks Henk’s PHR data before they meet to see how his health developed over the previous period. The other professionals do not use it yet.

Henk is dreaming of the perfect PHR, a PHR tailor-made to his health needs and lifestyle. He would like his medication data be added automatically to his PHR. Right now, he has to add all the medication data himself. He would like to see a link between his medication use and the effect it has on his health and wellness. He would like his PHR to be continually improved and re-adjusted to his changing health needs. Henk would also like to clearly view how he can affect his health through physical activity. He uses his smartphone as a tracker of daily activities and would like to see this information along with his sleeping patterns entered directly in his PHR. He would like to have this information added to get an integrated view on how to set and achieve his health goals. Henk firmly believes that it would help if his care team would use the PHR as well, even if that were only to look at summaries of new data collected since his last appointment. That would give them a more complete picture of his medical situation. This does not happen today, so Henk is proactively generating a summary of his health measurements. He discusses this summary with individual members of his care team during regular consultations. A standards-based PHR would have done that much more efficiently.

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1 Sarcoidosis: a mystery disease: [https://www.youtube.com/watch?v=WOG7orZIfGk](https://www.youtube.com/watch?v=WOG7orZIfGk) [accessed 31 July, 2017]

2 See Henk Bakker’s PHR video on [https://www.youtube.com/watch?v=KFtezTNzLSY](https://www.youtube.com/watch?v=KFtezTNzLSY) [accessed 31 July, 2017]
Preamble

Standards are found in practically every area of our daily lives, to the point where we often take them for granted. Without standards, products might not work as expected, they may be of inferior quality or incompatible with other equipment. In extreme cases, non-standardized products may be dangerous. Customers might then be restricted to one supplier; manufacturers would be obliged to invent their own individual solutions to simplest needs, with limited opportunity to compete with others.

The benefits of standards are many. Adherence to standards helps ensure safety and reliability. Standards enable devices to work together and provide a solid foundation upon which to develop new technologies and to enhance existing practice. Standards are frequently referenced by regulators and legislators for protecting user and business interests and supporting government policies. Standards play a central role in the European Union’s policy for a Single Market. Standards open up market access, provide economies of scale, encourage innovation, increase awareness of technical developments and initiatives and provide the foundation for new features and options, thus contributing to the enhancement of our daily lives. Mass production based on standards provides a greater variety of accessible products to consumers.

There is wide recognition of the relevance of standards to achieving the benefits of eHealth. Today’s healthcare landscape consists of a variety of care settings and stakeholders, which use many different information systems in their delivery of care. For many years, efforts have been made to improve eHealth standardisation activities with a view to producing outputs that are coherent and relevant. Despite these efforts there still appears to be a significant gap between those who develop and those who are expected to implement. On the one hand, the very aims and objectives of most healthcare systems across the world focus on improving continuity of care through the effective communication of patient information, supported by consistent and comparable data that can inform better decision making on matters of efficiency and effectiveness. On the other hand, the application of standards – which should address these very issues – is seen as complicated and expensive and with only limited success. As a result, there is reluctance to invest or participate in such standardisation activities.

What to do about this? We need to bridge this gap. Perhaps a starting point would be to set out critical success criteria for standardisation activities and their outputs:

- **relevance**: that standardisation activities are seen as relevant to business objectives and current activities
- **openness**: that standardisation is seen as an open and inclusive process which removes rather than presents barriers for progress
- **engagement**: that all parties contribute, from prioritisation of business requirements through development, implementation and maintenance
- **affordability**: that resulting standards are affordable, and demonstrating a clear return on investment
- **sustainability**: that the framework for development of interoperability standards is sufficiently open and flexible to allow adaptation and development as the solutions and market evolve.

*Jeremy Thorp, NHS Digital*
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1. Executive Summary

The eStandards project set out to advance eHealth interoperability and global alignment of standards. It was carried out by HL7, CEN/TC 251, IHE and eHealth competence centres in Europe, with support from the eHealth Network, ISO/TC 215, GS1, SNOMED International, IEEE11073 and IMIA. It joined up with stakeholders in Europe and globally, to build consensus on eHealth standards, accelerate knowledge sharing, and promote wide and rapid adoption of standards and profiles. Guided by the vision of a global eHealth ecosystem, where navigation tools guide people to safe and informed healthcare and where interoperability assets fuel creativity, entrepreneurship, and innovation in sustainable health systems, we envision a new generation of ‘live’ standards, called eStandards.

**eStandards will drive large-scale eHealth deployment and support the digital transformation of how we manage our health and deliver healthcare.**

The first wave of digitisation in healthcare has led to massive amounts of health data accumulated in health information technology systems serving primarily documentation purposes. Appreciating the need to electronically share information to deliver better health services, we gradually moved from passive documentation to active exchange and use of information. Nowadays, the availability of health data, combined with the rapid accumulation of citizen and health related data, brings opportunities for digital innovation, characterised by data driven knowledge creation and a greatly enhanced user experience. Improving the best practices of today, while creating room to test new innovative ways of eHealth deployment, has been the challenge of this project. Early on, we recognised that facilitating different speeds of development and dynamic governance, as depicted in Figure 1, would be important elements of a successful eStandards roadmap.³

![Figure 1](image)

**Figure 1: The need for coordinated standardisation at different speeds, as an infrastructure for innovation**

To illustrate this notion of eStandards in support of innovation, consider patient summaries, which is one of the focus areas of this roadmap. The European patient summary concept was conceived of to serve the cross-border level, for patients seeking emergency or unplanned care in another member

³ This understanding has been inspired by the pace-layered application architecture and bi-modal organisation of IT as developed by Gartner.
state under directive 2011/24 on patients’ rights to cross-border care. Nowadays, this work advances with the experts of member states collaborating in the CEF eHealth Digital Services Infrastructure program. In parallel, this work influences developments at the level of the community, the region, and the nation. The real impact of this roadmap, however, is at the top level of innovation and user experience where standards touch our lives, shaping our expectations of digital health tools, the available diagnostics, health scores, and the accessibility of the right information, at the right time, and in the right form.

In support of innovation, eStandards employ the tools of the digital age to engage all stakeholders in continuous collaborative development, deployment, evaluation, and refinement of interoperability specifications. The current processes, publishing formats, and organisation of standardisation need to be revisited with a view to embracing open innovation, practice driven improvement, and seamless integration with the tools employed in the development and deployment of eHealth solutions and services.

![Figure 2: The Health Informatics Standards Life Cycle](image)

At a rapid pace of ‘just-in-time’ disruption, Standards Developing Organisations need to join forces in cooperation with their ‘customers’, the practitioners of interoperability, to deliver quality, interoperability, and knowledge in a timely fashion and at an affordable cost. This effort needs to be taken in an inclusive and collaborative way, which looks outwards at the deployment of eStandards, listens to user experience, and rethinks standards and tools that support the full eStandards life cycle (see Figure 2). The eStandards life cycle smoothly combines various base standards in use case-based standards sets, supports testing, deployment, and feedback from implementation, enabled by user groups and educational fora.

Thus, with eStandards, the constituency of Standards Developing Organisations expands to include all stakeholders involved in the full life cycle of delivering and deploying eStandards. The crucial roles of patient and professional associations, national eHealth competency centres, provider and vendor associations, and various government agencies are therefore recognized.
2. Core Concepts of the eStandards Roadmap Methodology

The Roadmap proposed by the eStandards project is a Roadmap for allowing greater collaboration across the healthcare spectrum, bringing in the views of all users – citizens, healthcare workforce, researchers, vendors and health systems (purchasers). It takes as its goal the end point of the journey that it facilitates, the use of general and personal health information at the point of care, at the fingertips of individual citizens, as well as for biomedical, clinical, public health, and health policy research. The ultimate goal is to support innovative use of health information to drive sustainable health systems that meet the linked targets of efficacy, quality and access. That is health systems that deliver effective care to meet the needs of individual patients and populations.

Four core concepts are identified to make this happen. First of all, the recognition that trust by all parties involved in a dynamic flow of data is needed for general and personal health information to be used safely at the point of care and elsewhere throughout the health systems. Next, respect for differing perspectives of the stakeholders will have to be demonstrated for them to contribute to such trusted flow of data. Furthermore, dynamic flow of data is enabled by a reusable set of standardised eHealth artefacts, otherwise data will not be able to flow between eHealth solutions and the people and organisations that use them. Finally, eStandards will come to life in a concrete setting where stakeholders co-create, govern and align their solutions along the eStandards life cycle. The next sections describe these core concepts in more detail.

2.1 Trust and Flow: the basis of well-functioning health systems

The Roadmap methodology is founded upon the concept that the flow of trusted data is the basis of a well-functioning health system, which can drive healthcare delivery based on relevant information and knowledge at the point of need. In this context, the role of standards is seen as core to achieving those dual needs.

![Figure 3: Trust and Flow](image-url)

Trust and flow are grounded in the acceptance of four key changes that well-functioning European healthcare systems have to embrace:

- **increasing need, expectation, and cost** of healthcare resulting from the combined impacts of ageing populations, increased medical competence, and high investment in new medications and medical technologies;
• **changing nature of the doctor patient relationship** in which the patient is much more closely involved with his or her care and seen as an active partner in healthcare, demanding that patients have better access to information about their health and the preferred options for care and treatment that are available;

• **increased demand for more home based and mobile care** that is available ‘just in time’;

• a pressing need to **extend the capacity of the healthcare workforce** as the numbers of those remaining in or indeed entering the healthcare workforce reduce.

The role of eHealth solutions in addressing the demands set out above is evident. eHealth solutions are a key component of supporting greater interaction between healthcare professionals, monitoring patients on the move and at home, and allowing for a much more responsive care environment. Furthermore, judicious use of eHealth can be a core component of a health services change business case, as it can provide for better use of human resources, support greater patient compliance with recommended treatment, reduce bed demand and prevent acute episodes. The business case for eHealth is compelling in *Cost-Containment Policies in Hospital Expenditure in the European Union* and is therefore significantly dependant on the development and implementation of eHealth solutions that address the issues that health service planners and procurers are seeking to change in driving cost reduction and sustainability in health services delivery.

However, in order for such eHealth solutions to be more than local pilots and small home-grown solutions, a trusted flow of health data is required so that solutions can interoperate, can be scaled-up and remain sustainable within a healthcare system for as long as possible. This way, we not only allow developers to bring solutions to the healthcare market that meet the needs of patients and the healthcare workforce, but also comply with regulations and good practice guidelines and fit into the governance structures of health systems.

### 2.2 eStandards Compass: Respect for perspectives of stakeholders

If the development and full adoption of eHealth tools and solutions in healthcare delivery in Europe is described as a journey, it requires a map – hence the Roadmap. However, use of a map is greatly facilitated by a compass, which allows the user to orientate him- or herself with respect to his or her current perspective.

The concept of the compass in the eStandards Roadmap is used to indicate the general direction of travel to reach an end point, and the particular perspectives of key stakeholders and end-users, which should be taken into account when planning the journey (see Figure 4). A navigation system may suggest different routes depending on the nature of the vehicle to be used, current weather conditions, current traffic conditions, and preferred routes. In the same way, the eStandards Roadmap provides the Standards Developing Organisations and their constituencies, with a methodology to orientate themselves according to the perspectives of the key players who will be involved in the production, regulation and use of the standards. It also serves as a tool for communication with key

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4 See EUROPEAN ECONOMY Cost-Containment Policies in Hospital Expenditure in the European Union - a European Commission Staff Working Paper by Christoph Schwierz ISSN 2443-8022
players to embed the use of standards in their requirement setting, procurement frameworks and ultimately deployment of eHealth solutions in support of their personal, professional or health system goals and objectives.

The roadmap methodology therefore invites those developing or using standards to orient themselves to the unique but interrelated perspectives of the health system, the workforce, the citizens, and the market for digital health solutions. In order for the compass to remain up-to-date, calibrated to global trends as well as the local needs and issues, there must be opportunities for the creators and end users of the standards to be engage together with the four perspectives of the compass and the associated dynamics. It is for this reason that the concept of co-creation, further defined below, is important not only in standards development, but also in the constant evaluation of the tools which are used in standards development, testing, deployment and evaluation, including the compass depicted below.

A compass is an instrument used for navigation and orientation that shows direction relative to the geographic cardinal directions. The use of a compass entails understanding the difference between ‘true north’ and ‘magnetic north’. Magnetic north is the location where the magnetic field of the Earth points downward. True North, on the other hand, is the location of the axis on which the Earth rotates. If you spin a ball, you will find a point that rotates instead of traveling around in a circle. That is the axis, and that is what we call true north, and the key point in terms of orientating oneself. The concept of the compass and true north are often used figuratively and are used in eStandards to convey the idea of orientation of standards life cycle activities with respect to understanding and accommodating the different perspectives of the key actors who will ultimately use the standard.

![Figure 4: The eStandards Compass of Perspectives](image)

The concept is used in eStandards similarly to the way the concept ‘moral concept’ is used in common parlance. By placing ‘moral’ in front of the word compass, we evoke a clear picture of mental processes that points a person or organisation needs to adopt to plot a route. Just as a navigation compass can indicate true north, so a moral compass is said to help a person or an organisation fix true and consistent indicators upon which action can be based, balancing different interests and perspectives.
In the eStandards context, the idea is that an organisation maintaining a standard or a set of standards, can put itself in the shoes of each of the four key perspectives to understand their ‘true north’. By seeking to serve and balance the needs of the different perspectives, the organisation engages directly or indirectly with a much richer set of activities forming productive relations with a broad set of stakeholders, as it plots the course of the standard’s life cycle. The compass is therefore a tool integral to the road mapping process which will help an organisation better understand the needs of the people who will ultimately use the standard.

If we take the example of the interests of citizens as one of the key perspectives, the ‘true north’ of the citizen in a given healthcare situation may be the capacity to engage in his or her own care (or in supporting the care of a family member) effectively navigating the healthcare system. Therefore, if a standards organisation wants to develop a standard that accommodates this need, it must be able to understand it and more importantly understand its impact on the way in which the standard is developed, deployed and maintained.

2.2.1 The Citizen

In analysing the added-value of availability of and access to health information, we start out with the trend among patients like Henk, to whose memory the Roadmap is dedicated. Citizens, as Henk’s story reveals, increasingly need assistance to navigate the health system(s) online and offline. Citizens wish to be informed of the availability of healthcare services, their quality, and the associated costs as they form their health team. When they have made their choice, they want to meet with a professional team that is well informed and up-to-date about their particular medical situation and any relevant history they bring. At the same time, controlling the information being shared is crucial. In retrospect, citizens, and their circle of informal care givers, play an increasingly important role in the maintenance of their own health. Teaming up with them effectively through standardisation can nurture empowerment. Such empowerment in turn can be used by citizens to navigate the health system for prevention, care, and wellness; and can also support citizens in active involvement in health maintenance and care decisions.

As detailed in Deliverable 3.3, when a patient’s (or citizen’s) information is recorded using tools based on standards, it can be easily filtered, presented, and communicated in a way that is both safe and understandable for patients and professionals alike. Protection of personal information and patient consent also require standardisation to be effective across different platforms, when sharing information with different professionals and providers and potentially across jurisdictions. Standards for self-help services in the area of eHealth enable citizens to engage with different healthcare providers across the health system without having to constantly adapt to local systems and practices.

In Henk’s story, we learnt that he was unhappy that he was the only one entering data in his PHR, to change this reality takes more than technology, FHIR interfaces and IHE profiles. It requires a culture of data sharing, communication, and trust.

It is therefore of key importance that when a roadmap is plotted for eHealth solutions, the needs and desires of citizens are taken into account and that their perception of ‘true north’ is fully understood by standards developers.

2.2.2 The Workforce

Healthcare professionals’ practice has changed profoundly over the years, due to sub-specialisation, rapid pace of innovation, availability of immense amounts of information, relevant or not, and the changing practice of (medical) care in relation to other professionals and patients. Numerous studies
have found that the objectives and motives of professionals are quite different from what provider organisations and healthcare system administrators expect. Their main driver is to provide safe and high quality healthcare services, i.e. to do their job well and to do good to their clients, patients, and customers, and facilitate coordination and continuity of care for the patient across care settings and provider organisations. When the continuity of care is at stake, for instance when a patient is referred to another professional in a different organisation, sharing and using the information needed in different systems requires a high degree of standardisation of health information exchange.

The explosion of knowledge about support or treatment options and their effectiveness is a major challenge to all people engaged in healthcare. Important progress is shown when treatment decisions combine knowledge with individual patient characteristics, leading to precision medicine, rather than standard care plans for a standard patient. Establishing feedback loops within care teams and among professional groups, based on their actual daily practice, has shown to be a very effective and inspiring form of knowledge dissemination and even knowledge creation. Moreover, extending the feedback loops to wider professional and expert communities has helped in the quick dissemination of knowledge, education of the less experienced colleagues, and continuous professional growth for all.

It is therefore important that standards developing organisations can understand the perspectives of the health workforce, not only to be able to respond to their needs, but also to help them learn how standards will help in the adoption and productive use of new interoperable technologies, as well as in the generation of new ideas for application of new technologies. Digital health tools come as a two-edged sword to the workforce. Fragmented processes, excessive documentation, and digital health tools of questionable quality demand more and more time from health professionals as trust with patients and informal care givers rapidly erodes. This challenge to traditional patient-doctor relationships needs to be addressed by developing a better understanding of the interplay of health services with digital health standards, which frequently address only technical aspects.

However, to gain a professional’s trust, it is of core importance that eHealth standards are not built on preconceived ideas of healthcare processes, but rather build on the needs health professionals express, granting them a significant amount of control over the way they work with the system.

As demonstrated in Henk’s story, the use of standards in making targeted information available is at least as significant for the workforce, as it is for citizens and patients. Henk struggles with making his information available to his whole care team, even though he has a good overview and summary available in the PatientsLikeMe system that he uses as a personal health record. Standardisation of data and interoperability with the various systems his care professionals use is lacking. All he can do now is take a printed summary with him at the next consultation. His care professionals have no way of integrating that summary data into their own systems and must revert to re-keying available data by hand. However, as Henk’s story indicates it takes more than technology: organisational interoperability and a culture of information sharing, and trust are crucial ingredients.

### 2.2.3 The Health System

The health system perspective relates to governments and regulators that have responsibility for the operation of health services in a specific jurisdiction, as well as the healthcare provider organisations that deliver healthcare within that jurisdiction. Health outcomes of the population covered reflect the quality of the health system. In that sense, the health system is the provider of services, while the health workforce and citizens are the co-producers of health and the customers or beneficiaries, respectively. Policy makers need to make sure the system is sustainable, and the customers are happy.
Extensive research indicates that eHealth deployment can contribute to the overarching objectives of health systems by: “Improving the overall health of the population at an acceptable cost, whilst ensuring the quality, accessibility, and affordability of healthcare for all.” Insights in the relationship between prevention and treatment options, on the one hand, and health outcomes to be obtained, on the other, lies at the heart of a Learning Health System⁵, a notion that is quickly gaining momentum across the world. Evidence also suggests that eHealth services for personal learning in the management of one’s health, including prevention, are cost effective in certain areas. In addition, eHealth has been proven effective in reaching remote communities at an affordable cost. However, applications of eHealth that are productively integrated with the health system, remain local in scale.

In cross-border care, EU funded projects like epSOS, SemanticHealthNet, Trillium Bridge, and e-SENS, to name a few, but also the experience of patients and professionals in teleconsultation and telemedicine, show the necessity and feasibility of cross-border deployment of eHealth services.

Large-scale deployment of eHealth systems and services, conforming to standards, is deemed an essential ingredient of a number of health policy objectives, aiming at collecting evidence as we understand and continually improve healthcare practices. Transparency of healthcare delivery, through readily available healthcare data for secondary use, can drive the decisions to move the provision of care away from the more costly specialised centres and more into the home and under the personal responsibility of the patient and his or her informal caregivers, if the outcomes are similar or at least acceptable. Specific examples of eHealth systems and services in support of such health system policy objectives often found across the western world, place more emphasis on community care, staying at home longer, self-management of chronic conditions, dependence on informal care givers, etc. Compliance to standards adds to the predictability of costs, the agility of the health system and its ability to capitalise on the results and best practices of other health systems. Standards sets and associated tools are needed to help achieve and build upon this degree of transparency and performance within and across health systems.

Evidence suggests that eHealth services for personal learning in the management of one’s health, including prevention, can be very effective. Again, we can consider Henk, who is looking for data from regular medical tests and diagnostic examinations be combined with health monitoring data from activities of daily living and medication intake, to inform his ability to understand, control and eventually take responsibility of managing his disease. In this case, the health system takes the role of offering regular guidance and support in a timely manner. Balancing offerings of just in time face to face and routine remote appointments or eConsultations, becomes a pressing issue that digital health tools are able to solve and health systems urgently need. Supporting rules and guidance to employ these services lead to lower costs and higher availability, trust, and impact than having health system personnel provide face-to-face coaching to each citizen exactly the same way. In addition, eHealth has been proven to be very effective in reaching remote communities at an affordable cost.

⁵ The Learning Healthcare System: Workshop Summary, Institute of Medicine, Roundtable on Evidence-Based Medicine, 2007, https://books.google.gr/books?id=VWMiwvCZOJoC
2.2.4 The Market

The variety of health services needed in a well-functioning healthcare system makes it hard to agree on a common eHealth deployment strategy for a single vendor that serves multiple provider organisations. Standards enable the deployment of specialised digital Health services on top of a variety of core systems. For example, the “Smart on FHIR” project works on apps that can operate on top for different installations of the same or different health information systems, focusing primarily on the information needs and user experience preferences of end users. Already core systems vendors are being pushed into working together to provide a suite of standardised interfaces for advanced eHealth services from other vendors.

Explicit and consistent reference to standards sets in the procurement of eHealth systems and services across the provider community will help shape the supply side of the market. In order for this to happen, however, it is crucial that standards sets, i.e. a coherent set of standards and standards artefacts that support a specific use case, are part of the trusted dialogue on interoperability across the provider and vendor communities. Here again we see therefore the importance of aligning the perspective of the vendor in standard development work, because the vendor needs to be able to build standards-based solutions to meet the demands of patients, doctors and health systems – Henk’s story again serves as a useful illustration here.

In eStandards we work with the idea of plotting a journey – developing a roadmap – using the compass to turn to the perspective of four different groups who will ultimately use the standard: citizens, health workforce, health system, and digital health market.

These perspectives were previously introduced in the case for formal standardisation in large-scale eHealth deployment (deliverable 3.1 of the eStandards project) and are further elaborated below.

2.3 eStandards Roadmap Components: reusing eHealth artefacts

The eStandards Roadmap did not spring from a vacuum. Its early stages of development focussed on the existing standards artefacts and reflected on how they met the demands of the Refined eHealth European Interoperability Framework (ReEIF).

The eStandards’ roadmap work developed from an overview of the state-of-the-art and development needs in areas that we have identified as roadmap components. These components play a significant part in the collaborative development and deployment of standards sets, and help identify the “waypoints” which form an essential part of the journey. The CGA model, as outlined above, will then help plot the course to reach these “waypoints” in an appropriate order, taking into account the prevailing interests and needs as identified by a judicious use of the compass.

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7 https://blog.interfaceware.com/top-7-best-smart-fhir-apps/
In developing the first iteration of the Roadmap (presented in Deliverable 3.3), the eStandards partners examined fifteen categories of standards, which were developed from the Refined eHealth European Interoperability Framework (ReEIF), as endorsed by the eHealth Network in its 8th meeting (November 2015). Based on the Interoperability layers of the ReEIF, these fifteen sets of components (see Figure 5) are key to the delivery of eHealth and each in turn having particular needs for close attention from standards developing organisations.

The road mapping methodology proposed here is based on the understanding that to a certain extent these fifteen core component areas are able to fulfil the present needs from the four perspectives explored with the Compass. Several gaps need to be filled and standardised artefacts will be refined based on the changing realities of the needs of the users, the technological trends, the regulatory frameworks and the governance systems in which they operate.

**Co-creation, Governance and Alignment (CGA model)**

A compass and a set of waypoints is however of little use without a map. To develop a successful journey we need to understand not only the prevailing winds of demand (the often competing demands the four perspectives), but also to understand the key modes of travel needed along the journey. The eStandards Roadmap is therefore not purely a map for defining a route to a destination, but also a methodology for a successful journey.

The methodology proposed by the eStandards Roadmap is a model for inclusive and responsive standards life cycle, which favours an efficient and dynamic use of standards to support best use of data at the point of care and in research to drive an efficient patient centred healthcare system based on robust governance, trust and innovation.

The methodology for standards development - and for the creation of a specific roadmap for adopting a specific set of standards – is based on upon the idea of a continuous flow between three acts of design, development, and interaction: Co-creation, Governance and Alignment (Figure 6).
Co-creation - adoption of standard sets and tooling for local specification through collaboration of the stakeholders throughout the process - development, deployment, testing, certification and monitoring.

Governance - recognition and referencing of legal and organisational rules in development of a standard, and conversely of the recognition of standards in the development of organisational rules

Alignment - the ability to remain flexible, to use evidence constructively in order to refine and maintain the co-creation loop as a continuous virtuous circle of alignment between all players in the system, and across standard sets.

The methodology for standards development, deployment and maintenance throughout its life cycle – and for the creation of a specific roadmap for adopting a standards set – is based upon the idea of continuous flow between three acts of development and interaction: co-creation, governance and alignment.

Co-creation

While the term co-creation is something of a buzz-word at the moment, and many people are talking about it as if it were new, the concept has in fact existed for as long as modern medicine. The Hypocratic Oath, believed to have been written between the 5th and 3rd century BC states: “The physician must not only be prepared to do what is right, but also make the patient cooperate”.

While we may now use less harsh language and talk of supporting and empowering the patient (rather than making him or her cooperate), it is clear that more than two thousand years ago health workers understood the importance of engaging the patient.

Our definition of co-creation however involves not only the patient, but also other actors in healthcare, notably those represented under the four primary perspectives/axes of the Compass: citizens (including patients), the health workforce, the health system, and vendors. Furthermore our understanding includes the following elements:

- Co-design of services – co-planning of health and social policy, co-prioritisation of services and co-financing of services, co-commissioning;
- Co-delivery of services – co-managing and co-performing services
- Co-assessment – co-monitoring and co-evaluation of services.

Co-creation, however, is not simply “working together”. The concept of co-creation is based on acknowledging the difficulties in healthcare to work together across a wide spectrum of players. It has a built-in provision to address conflicts of interests and opinions up front. It does so by having the participants in the process learn to understand each other’s perspective in the course of the development of a product, work method, or indeed a standard.

The objective of co-creation in healthcare, whether it is in terms of patient experience, an innovative tool, a new process or a product, is to enhance the effectiveness of the total development process. It seeks to facilitate the selection and provision of the right response or intervention at the most economical level of cost, while, at the same time leveraging the best possible chances of safe and sustainable adoption.
Looking at the concept from a patient perspective, one can readily imagine that not only personal physical aspects matter to this, but also attitude, apprehension, support, information and education given for the patient. From a health system perspective, it will need to include things such as the overall governance system, existing rules of operation, legal requirement and perhaps most importantly the assurance of continuity of workflow. For the healthcare worker the importance of workflow, ease of use, patient confidence and adherence to governance procedures will also rank very high; and finally from the vendor perspective, engagement in co-creation is very likely to include emphasis on overlap and synergy between existing solutions and tools and newly proposed solution. This will include a focus on the use and integration of existing standards as well as a thorough understanding of workflows and capacity to adhere to legal requirements.

From this description, it can be seen that the development of a co-creation strategy in the eStandards context will be highly dependent on a careful and thorough use of the concept of the Compass. In order to ensure that the right people are in a co-creation process and that their perspectives are well understood by all participants, it is crucial that adequate and appropriate tools are used to gather their views and allow them to be shared and understood.

The objective of this document is not to provide a complete guidance on the co-creation method to be used. That will be dependent on the issue to be addressed, the existing relationships between the participants, and the time and finances available. The objective here is simply to highlight the importance of building in a stage of co-creation into every aspect of standards development to ensure that the needs of all users are met as best as possible and to drive uptake and deployment of the standards as widely as possible.

A thorough analysis of the literature of co-creation in health services has been undertaken by Professor Greenhalgh’s team at Nuffield Department of Primary Care Health Sciences, University of Oxford and is available in The Milbank Quarterly.

**Governance**

In the description of co-creation above, the term ‘governance’ was used several times. In our CGA model, it is treated also as a separate gear, moving at its own right and speed. This is because standards are very often closely linked to the governance of healthcare systems and healthcare work flows. It is important to note here that the term ‘governance’ is used in a wide sense, much as it is used by the WHO.

The WHO describes governance in the health sector as covering a wide range of steering and rule-making related functions carried out by governments/decisions makers as they seek to achieve national health policy objectives that are conducive to universal health coverage. Governance is therefore both a regulatory and a political process that involves balancing competing influences and demands. It includes:

- maintaining the strategic direction of policy development and implementation;
- detecting and correcting undesirable trends and distortions;

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• articulating the case for health in national development;
• regulating the behaviour of a wide range of actors - from healthcare financiers to healthcare providers; and
• establishing transparent and effective accountability mechanisms.

The WHO notes that beyond the formal health system, governance means collaborating with other sectors, including the private sector and civil society, to promote and maintain population health in a participatory and inclusive manner. Furthermore, governance should also be concerned with managing resources in ways that promote national leadership, contribute to the achievement of agreed policy goals, and strengthen national health systems. At a level of legislation, the capacity for exercising governance functions is greatest at the national level, but note that the term also covers the steering role of regional and local authorities, as well as the internal governance systems of a given health entity. The hospital board or local medical committee is therefore also a key player in governance as understood in the CGA model.

Respecting the governance element of the CGA model requires that regulators are involved in the standards life cycle activities and standards developers are fully aware of the regulations, which impact upon the use of standards. Finally, governance requires a constant process of monitoring and evaluation to allow alignment to be made with standards or regulatory and governance frameworks. This is illustrated in Figure 2, the eStandards life cycle, pictured as a series of connected development activities in an iterative process of continuous quality improvement.

Alignment

The concept of alignment within the CGA model is the element, which drives the cyclical and flowing nature of CGA. It is the element that ensures the changes in the perceptions of stakeholders or changes in governance are accommodated into projects and initiatives already underway. Within standards development work, the alignment element requires activity principally on the part of the standards developing organisations which must remain vigilant to potential changes in governance or stakeholder concerns and needs.

A key requirement of including alignment activities is to ensure that appropriate monitoring and feedback systems have been set up to make sure that relevant changes can be captured and addresses. While the alignment aspect is therefore less active, it is in many ways also the most crucial. As Greenhalgh and colleagues have pointed out, co-creation efforts often get off to a great start of a wave on co-creative enthusiasm. They tend to fail when stakeholders are not integrated on a long-term basis and they experience their participation as a ‘tick box’ activity rather than a true commitment to co-creation.

Alignment is arguably not a separate element of the CGA model, but defines the process as a whole, in which all relevant actors are able to bring their needs, desires and achievements to the table in order that solutions are identified and discussed, collectively and collaboratively. It is worth noting however that the alignment element may also be used to describe the negotiated relationships between actors, in which they seek to align to one another for best outcomes. For example, one may consider the activities at regional or member state level as the eHealth DSI becomes operational.

Another interesting example of new approaches to alignment can be seen in the emerging pricing and reimbursement models for pharmaceuticals, which are currently in evolution. One such example, the so called BeNeLuxA model, sees four sovereign countries (Belgium, Netherlands, Luxembourg and
Austria) working together to develop new approaches to pricing negotiations, even though European law provides that such negotiations are conducted at a national level. Recognising the power of greater numbers, the four countries are aligning elements of their individual systems to be able to negotiate better prices on a collective basis.

Translating this experience to the field of eHealth standardisation, we can see the value of flexibility and alignment, which may entail relinquishing some national norms to benefit from the greater capacity of internationally agreed norms. It also means striking the right balance between global standards and their locally adapted implementation guides.
3. The eStandards Roadmap Methodology at Work

The key take-away from the description of the core concepts of the eStandards Roadmap Methodology is that the development, implementation, evaluation and further refinement of standards must be undertaken in an inclusive way that is equipped to take their perspectives on board at all key way points.

Applying the eStandards Roadmap Methodology as set out above has three core steps (see Figure 7):

1. Using the concept of the eStandards Compass of four perspectives, identify the actors from across the healthcare spectrum who may have an interest in the way in which standards-based solutions are used. Develop appropriate ways of educating them about the value of standards and develop suitable ways of collecting and using their needs. The imperative to provide feedback and acknowledgement is crucial, or the well of co-operation may dry up.

2. Assess the Use Cases, Roadmap Components, and standardised artefacts that already exist and critically assess the extent to which they are able to drive trust and flow of data. Anticipate what is needed to move to the next stage and beyond.

3. Once the needs have been identified and the compass points calibrated, develop a co-creation-governance-alignment process:
   a. Develop tools for co-creation, look beyond the usual players to identify fields where lessons may be learned and find stimulating ways of drawing players together to learn and develop collaboratively.
   b. Examine the validity of the governance frameworks on which an organisation is built and run. If these are no longer fit for purpose, challenge them and seek to adapt rules to fit needs and capacity in dynamic flexible ways.
   c. Engage in a constant flow of alignment, where the parties in co-creation are adapted to fit need, where governance structures are challenged and where new models of alignment can be embraced.

The activities outlined above help create specific roadmaps for a given topic or focus area. In this methodology, we combine the following three key tools or concepts:

1. Compass of perspectives to inform the needs for trusted flow of data;
2. Roadmap components, helping to identify supporting standardised artefacts; and
3. CGA model to define the necessary actions to be taken or supported by Standards Developing Organisations working collaboratively with all relevant stakeholders.

Based on the application of the methodology, a collaborative course can be plotted in the form of a joint programme of actions at the appropriate (local, regional, national, European or global) level. Applying the methodology to a specific area of eStandards development for standards-based eHealth deployment will yield an eStandards Roadmap of actions. The development of the roadmap itself is to be initiated within a wider program of health innovation and real-world benefits for that specific area of health management and healthcare delivery. The actions identified in the eStandards Roadmap will, in turn, be carried out in the context of this wider program, to safeguard the linkage of the eStandards delivered with the support they provide for standards-based eHealth deployment.
In order to demonstrate how the concepts of the eStandards Compass, the Roadmap Components, and the CGA model work in practice, suggestions for key way points and considerations are explored for four areas of healthcare on the basis of the three-part process: needs to be met, standardized artefacts to be deployed, and actions to be taken in co-creation, governance, and alignment.

The needs to be met can only be articulated through the involvement of representative eHealth stakeholders e.g. citizens, patients, informal care givers, health professionals, vendors, researchers in different roles, as we approach them through the lens of distinct perspectives. The standardised artefacts are to be considered in designing new projects or initiatives and are to evolve with input from testing, implementation, and operational activities. Thus, actions to be taken are to be integrated into
and coordinated with the work plans of the individual initiatives shaping the future of the specific area of healthcare at hand and its interaction with the wider societal environment.

The four areas of healthcare were selected involve complex issues in healthcare delivery, which have particular relevance to European eHealth in view of the emerging data economy and the digital single market for health information technology:

- Unplanned and Emergency Care using the Patient Summary;
- Chronic Disease Management (such as Diabetes T2, CVRM, COPD);
- European Reference Networks for Rare Diseases;
- Common Identification of Medication across the above three care areas.

These four areas have been chosen because they have especial relevance to healthcare within the European policy setting. It is worth noting here that, with some limited exceptions, the European Union has no legal competence to adopt EU law in the field of healthcare, as healthcare is a matter of national competence according to the EU’s founding or ‘constitutional’ document, the EC Treaty. The EU does not define health policies, nor the organisation and provision of health services and medical care. Instead, its action serves to complement national policies and to support cooperation between member countries in the field of public health. However, good health is a major concern of European citizens and the European Union works for better health protection through its all policies and activities, in accordance with Article 168 of the Treaty on the Functioning of the European Union. EU action on health issues aims to improve public health, prevent diseases and threats to health (including those related to lifestyle), as well as to promote research and to complement national policies and to support cooperation between member countries in the field of public health.

The role of the EU in eHealth is to support the development and adoption of tools and services using information and communication technologies that can improve prevention, diagnosis, treatment, monitoring and management. The EU therefore seeks to promote the uptake of eHealth solutions that can benefit the entire European citizen community by improving access to care and quality of care and by making the health sector more efficient. This includes information and data sharing between patients and health service providers, hospitals, health professionals and health information networks; electronic health records; telemedicine services; portable patient-monitoring devices, operating room scheduling software, robotised surgery and blue-sky research on the virtual physiological human.

In accordance with these general aims, and supporting the right of freedom of movement of European citizens, the four issues discussed in this chapter are in line with EU health policy, insofar as it exists:

- Unplanned and Emergency Care – is provided for within Directive 2011/24/EC on Cross-Border Care;
- Chronic Disease Management – is addressed within the European Public Health Programme;
- European Reference Networks for Rare Diseases – are provided for within Directive 2011/24/EC on Cross-Border Care;
- Common Identification of Medication across the above three care areas – as provided for by the EU legislation on Safe Medicinal products, in particular Commission Implementing Regulation (EU) No 520/2012 on Pharmacovigilance.
3.1 eStandards Roadmap for Unplanned and Emergency Care

The term unplanned or emergency care is a generic term, which covers all healthcare services provided to patients, which was not foreseen and hence not planned. It includes primary and secondary care, ranging from acute emergencies and ambulance assistance, to unplanned GP visits, often to a GP that does not regularly care for the patient, as when a patient has to seek primary care while away from home.

At a European level the concept of unplanned and emergency care is addressed in policy and legislative measures to support patients who need to seek unplanned care when in the EU but not in their usual country of residence. Following many years of complex cases in the European Court of Justice, in 2011 the EU Directive on the application of patients’ rights in cross-border healthcare was adopted, clarifying and codifying the rights of European citizens to receive care in a Member State other than the State in which they are insured. The Directive has now been transposed by all Member States (albeit with a delay in some countries), and provides for the provision of planned and unplanned care across the EU, to EU citizens who need care outside their usual country of residence.

Unplanned and emergency care, whether provided in the patient’s home country or abroad, is highly dependent on ensuring that healthcare professionals have access to the right information about the patient. The patient summary - including treatment, diagnoses and medication - is therefore a core component of safe and efficient unplanned or emergency care. However, a number of other components are also relevant. These include issues related to security, such as secure identification and authentication of healthcare workforce members accessing information, secure transfer of patient data, and issues related to data assembly and exchange, including standardised artefacts such as templates and protocols.

Whilst a number of these artefacts exist, and standards to underpin their use have been developed, more work is needed to ensure their uptake by key programs like the eHealth Digital Services Infrastructure, including the National Contact Points that provide access to the national health information infrastructure.

The activities to produce an eStandards Roadmap for Unplanned and Emergency Care link directly to the activities of the JAseHN programme and the eHealth DSI that is currently being created with CEF funding. Both take the Guideline document for a Patient Summary for unscheduled care, as adopted by the European eHealth Network in 2016, as a foundational policy document. Alignment with patient access to and the portability of EHR data is apparent, however there seems to be little commonality yet in the way EHR data are being treated at a national level. National contact points for eHealth are linked to specific national EHR interoperability frameworks. These national frameworks often limit the degree to which identified needs for trust and dynamic flow of structured data can be addressed. Further development would benefit from a coordinated approach and broad availability of eStandards for Unplanned and Emergency Care, shared across the regional and national levels throughout Europe.

Making the Patient Summary, as specified for unplanned and emergency care, digitally available to citizens is seen as important step in the adoption of such a summary. A digital Patient Summary could serve as a starting point in exploring the health data of an individual and thus, as a platform for innovation. Portugal, for instance, is already providing to its citizens parts of such a summary in an extensible mobile app of digital cards as a first step in digital access to health data.
Adopting the CGA model of eStandards would facilitate quality management and continuous improvement of this functionality towards better-structured data through validated semantic specifications both in terms of terminology and content structures. The HL7 and CEN standardisation efforts towards an International Patient Summary (IPS) specification are an important step that maintains informal links to the eHealth DSI semantic group and several national programs.

However, these efforts do not yet fully benefit from a broader agenda that considers the full range CGA actions necessary to address the needs of unplanned and emergency care across the continuum, including topics such as mobile health or engaging the network of healthcare and informal care providers involved in crisis situations.

The efforts of the Joint Initiative Council on the Patient Summary Standards Set, reveals the complexity and importance of connecting the pieces in a live ecosystem. Providing for IPS validation and conformance testing through supporting actions such as the IHE Connectathon process is important, but not enough. We need to support the full eStandards lifecycle transparently, connecting the different complementing steps and initiatives, applying co-creation, governance, and alignment every step of the way.

Extending the IPS to other areas, beyond Unplanned and Emergency Care, whilst making full use of the efforts that have been put into the patient summary implementation thus far, is yet another area for eStandards Roadmap development. Bridging to the groundwork that the Trillium-II project is doing for creating a global community of digital health innovation and addressing the mobile health community gives the opportunity to reflect on the connections between a patient summary and a health summary supporting every citizen throughout their lifetime. That would open the way to reflect on an eStandards roadmap for patient summary data in the broader societal context catalysed by the emerging data economy.

The full account of applying the methodology appear in the full roadmap document available from eStandards-project.eu website.

3.2 eStandards Roadmap for Chronic Disease Management

Chronic diseases are diseases of long duration and generally slow progression. Chronic diseases, such as heart disease, stroke, cancer, chronic respiratory diseases and diabetes, are by far the leading cause of mortality in Europe, representing 77% of the total disease burden and 86% of all deaths. These diseases are linked by common risk factors, underlying determinants and opportunities for intervention. Some types of cancer and also certain mental health conditions are being regarded as chronic diseases that merit a similar approach.

The European Union per se does not have a direct chronic disease management policy, but recognises that chronic diseases are rising in Europe and are a major burden to health systems. The EU undertakes measures to support Member States in responding to chronic diseases and establishing good chronic disease management systems. The European Commission has established an EU Expert and
Stakeholder Group Network on Chronic Diseases\(^9\) as part of the EU Health policy platform. However, so far this network is not open to standards organisations and has as yet not given significant consideration to for digitisation issues.

On the other hand, given the provisions of Article 168 of the EU Treaty, the EU is entitled to take action at EU level to act as a catalyst to strengthen prevention for chronic diseases. This includes political support, financing instruments, and exchange of good practice and cooperation of Member States on prevention of chronic diseases.

Using these pathways, the European Commission has supported a number of research projects and, working across Directorates General, has supported work on standards for chronic disease response, including standards for registries, guidelines for apps and eHealth tools for direct use by patients. It has funded the Joint Action CHRODIS, in which 71 partners collaborated from 2014 to 2017, with a final conference in February. The scope of CHRODIS was limited to health promotion and primary prevention: chronic diseases can be preventable or delayed due to identification of “risk factors”, with further focus on management of Diabetes Type 2 and multi-morbid chronic diseases. Partners worked together to identify, validate, exchange and disseminate good practice on chronic diseases and healthy ageing and to facilitate its uptake across local, regional and national borders.

From the perspective of the eStandards project, there is great opportunity to further develop and drive deployment of standards that can support chronic disease management at Member States level and for further European and global collaboration. This however, has to be woven into considerations of the digitisation of health services.

Chronic diseases in Europe are responsible for 86% of all deaths and 77% of health and long-term care expenditure. Thus, chronic disease management attracts a lot of attention from eHealth innovators. This is apparent from the number of eHealth applications and apps that cater to the needs of people with specific chronic conditions. For instance, the Apple AppStore holds over 1,000 apps that mention diabetes in their description. In addition to the traditional healthcare perspective, supporting care pathways and specific interventions for (self) management of the disease, a lot of attention is given to the broader spectrum of life style and health management topics, including nutrition and fitness advice & monitoring. Facilitating citizen interaction with healthcare providers, mhealth if widely adopted and integrated can improve quality of services and better planning / management by healthcare systems, resulting in annual savings in Europe estimated at €69 billion. However, only 18% of European citizens have used online health and care services in the last 12 months.

This raises the question of quality and effectivity of the applications. Similarly, consumer devices that provide measurements and sensor data electronically need some form of validation for use in personal health management. The regulatory framework for medical devices traditionally aims to address such issues, but the regulatory cost would be prohibitive for small and medium enterprises that typically produce such innovative apps and for the consumers that use them. Moreover, the medical perspective is often not relevant for the more life style oriented apps. A multi-stakeholder evaluation system that engages patients and informal care givers in addition to technologists and health

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professionals could be employed\textsuperscript{10}. In some countries, similar actions are already being carried out by patient organisations. The adoption of eStandards by the providers of these apps might weigh in on the evaluation of apps, in case that addresses a clearly defined need from the perspective of the patient organisation.

The Staff working document\textsuperscript{11} on the Digital Single Market strategy, which presents the progress made since 2015 proposing new actions, identifies numerous examples of proven digital health programs that contribute to reducing the prevalence and burden of chronic disease. It notes that these programmes, unfortunately, remain at small scale due to differences between European health and care systems, lack of interoperability solutions and low awareness by authorities of co-investment opportunities.

![Figure 8: The Flower Model for Age-friendly Development (WHO, 2007)](image)

Recognising that chronic diseases are more prominent among elderly people, linkage to the European Innovation Partnership for Active and Healthy Ageing and similar initiatives is welcome, to provide for easy navigation and integration across the digital services that support, for instance, self-management and independent living. The midterm review of the digital single market\textsuperscript{12} references digital health tools and priorities that will be addressed in focus areas of operationalising the Active and Healthy Ageing Blueprint\textsuperscript{13}.

The PROGRESSIVE project is aimed at bringing together standardisation initiatives in this space that go beyond healthcare to touch upon living spaces and transportation, among others. Thus, the scope of the PROGRESSIVE project is much broader, but does include “community support and health services” as one of the key areas for collaborative standardisation (see Error! Reference source not found.). The project has expressed an interest in adopting the eStandards CGA model and contributing to

\textsuperscript{10} See for example myhealthapps.net
\textsuperscript{11} ec.europa.eu/newsroom/document.cfm?doc_id=44542
\textsuperscript{13} ec.europa.eu/newsroom/document.cfm?doc_id=40787
eStandards roadmaps where appropriate. Especially the recognition of the contribution by the elderly themselves in standards development is a key perspective that can be expressed through application of both the eStandards Compass and the CGA model.

So far, information systems, disease registries and data standards in the area of chronic disease management have not adopted the multimorbidity care model (MCM) as developed through the Joint Action CHRODIS\(^\text{14}\). An eStandards Roadmap for Chronic Disease Management could well provide the necessary insights in how to adopt MCM within the information systems and standards that support the management of chronic diseases.

In terms of public health and primordial prevention\(^\text{15}\) within the context of chronic disease management, research and surveillance are needed to support the identification of risk factors and the efficacy of interventions. Such research and surveillance data will come from longitudinal studies that are linked to both healthcare and lifestyle data sources. Exploiting various existing data sources, including personal health data, could contribute to a better understanding of primordial prevention of specific chronic conditions. Creating such accessible data sources is a key enabler of eStandards.

Care should be taken not to treat chronic disease management as an isolated topic. Already in the course of the JIC Patient Summary Standards Set initiative, the clinicians involved were keen to point out that information pertaining to chronic diseases that a patient might have could also be of key value in unplanned and emergency care. To take this further, the European Society for Hypertension has expressed an interest to work with the Trillium-II project on making the International Patient Summary part of their initiatives around self-monitoring and self-management.

The full account of applying the methodology appear in the full roadmap document available from eStandards-project.eu website.

### 3.3 eStandards Roadmap for European Reference Networks for Rare Diseases

An estimated 30-40 million Europeans are affected by rare and complex diseases.\(^\text{16}\) In 2017, the European Commission formally launched 24 European Reference Networks (ERNs) which bring together healthcare professionals working in rare diseases across Europe. ERNs were developed to allow healthcare professionals to work together to support patients with rare conditions or other conditions which need highly specialised therapeutic procedures. ERNs are a response to the need for a secure method for sharing expertise across the EU to better serve those patients living in countries with a very low prevalence of their disease, where they may in fact be the only patient their healthcare professional

\(^{14}\) chrodis.eu/

\(^{15}\) While primary prevention is about treating risk factors to prevent a chronic disease, primordial prevention refers to avoiding the development of risk factors in the first place.

\(^{16}\) ec.europa.eu/newsroom/sante/newsletter-specific-archive-issue.cfm?newsletter_service_id=327&newsletter_issue_id=3546
has ever treated with their rare condition. The ERNs address the healthcare professional need to access the knowledge, experience and case histories in other EU countries. Faster diagnosis and more personalised treatment of rare and complex diseases can be achieved if scientific expertise and data are pooled across borders, significantly reducing the 5.6 years on average that it takes currently to diagnose a rare disease in Europe.

The ERNs are designed to be tools for allowing expertise, rather than people, to travel. When a patient is treated with the support of an ERN, the patient’s care will remain the responsibility of their usual healthcare professionals. That care will however be enhanced by the support the local healthcare professionals can gain from having access to their counterparts in other countries who have a more extensive experience of the given condition.

On a technical level, the ERN(s) are constructed to allow healthcare professionals to share patient data securely through the ERN Clinical Patient Management System, known as the ‘CPMS’. In order to operate safely and to integrate easily with the care systems operating in the country where the patient will be treated, it is of paramount importance that the standardisation challenges of ERNs are met. This includes issues such as a common consent framework to allow healthcare professionals to share patient data in full compliance with the law, common languages and coding models to ensure that shared data are understood as intended, common authentication and identification systems for healthcare professions so that transparency and traceability of data sharing and data provenance can be ensured.

The present first phase of ERN’s provides also for a patient information portal on ERNs, but at present they are not designed to allow patients to be actively engaged in the consultations. It is yet unclear if patients will be entitled to request use of an ERN consultation under either the Cross-Border Care Directive or under the Social Security Regulation, both of which cater predominantly for situations in which patients travel to other European countries for treatment.

However, the Cross-Border Care Directive clearly envisages the use of eHealth, having established both the eHealth Network and the ERNs, and can therefore also be used as a legal basis for patients to become more directly involved in accessing ERN services directly. To achieve this, further phases of development of the ERNs will need to build in greater involvement from patients and non-specialist care providers and will also need to ensure that Standards Developing Organisations are included in planning and development work. This way, later iterations of the CPMS will likely be developed to ensure interoperability with the wide range of data sources that are needed to drive use of ERNs to their full capacity, including sharing of access to full records, images, lab reports, direct communication with patients, integration on patient generated data from implantable and wearable devices.

In terms of creating standardised artefacts for European Reference Networks, there is already quite a lot of material to work with, that has been created through various projects and programs and can now be made part of the eStandards Roadmap. A minimal data set representation for patient registries has been produced by the EUCERD Joint Action (2012-2015)\(^\text{17}\), which has supported the Commission Expert Group on Rare Diseases. In this effort, collaboration has been established with the EXPAND

concrete engagement, clear governance, and alignment with the eHealth standardisation activities has not been established yet, although early steps have been taken through the RD-Connect Joint Action18. The Joint Action RD-Action includes activities on further development of the Orphanet database of rare diseases. The use and electronic interaction with such a database could benefit from a clear positioning as part of an eStandards Roadmap, making sure that the systems and tools that the healthcare professionals across the EU use in the delivery of care can interact in an appropriate and hassle-free manner.

The Commission initiative to create Clinical Patient Management System (CPMS) in support of ERN activities has taken off with a focus on a collaboration platform for healthcare professionals, allowing them to disclose existing patient records, images, lab results and other data for joint consultation purposes. In the next steps, it should be extended to include patient data or integrated with third party health record systems both personal and organisational, both for clinical and for research purposes. That would give people the opportunity to make informed choices about their health and care and realise people centred care. An eStandards Roadmap for ERN’s would contribute greatly toward developing the joint use of clinical patient data, both in the daily care in the local care setting as well as to gain expert advice from ERN consultation. Moreover, the inclusion of patients and informal caregivers in the expert teams will be facilitated by trusted flow of data across the personal digital health environment. Exploring co-creation in the current state of development of the CPMS seems ideally suited for a collaborative development of an eStandards Roadmap for European Reference Networks that builds upon the combined expertise of rare diseases, health informatics and eStandards.

The full account of applying the methodology appear in the full roadmap document available from eStandards-project.eu website.

3.4 eStandards Roadmap for Common Identification of Medication

The need to standardise the definition of medicinal product information was at first recognised in order to facilitate the identification and exchange of such information in the context of pharmacovigilance activities.19 For instance, once medicines are identified as causing Adverse Events (AEs), it is helpful when this information can be shared quickly across the globe. Using a harmonised approach to identify and describe the medicinal product involved in an AE, is critical in ensuring accurate analysis and unambiguous communication across jurisdictions. Whilst the initial driver was pharmacovigilance, the health arena recognised the need to expand the scope of the initiative to support wider regulatory activities (e.g. clinical trials and inspections) and healthcare practices such as the prescription and dispensation of medicines.

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) was tasked, with support from the European Commission, to engage Standards Developing Organisations for the development of what is now known as the IDMP set of standards.

18 rd-connect.eu/
published by ISO. This standardisation activity was carried out under the auspices of the JIC with considerable contributions from its members, in particular ISO, HL7, GS1, and CEN.

As is apparent from the description of the other focus areas, medication is a crucial component when sharing patient health data and setting up registries of patient data for research and health management purposes. The scope of this area is therefore much broader than the initial idea of pharmacovigilance. Rather, it seeks to find a way for common identification of medication across the full spectrum of eHealth applications, starting with the three focus areas described in the previous sections.

By applying the methodology for eStandards roadmap development to this common identification of medication, a number of key actions have been identified. These actions are to be embedded in an overall programme for improving the use of medication data, including implementation of IDMP, in support of the aforementioned regulatory activities and healthcare practices. At a European level, both the EMA implementation of IDMP and the roll-out of ePrescription through the eHealth DSI are important initiatives that could propel the deployment of eStandards for the identification of medicinal products.

Currently, activities have been set in motion to implement the ISO IDMP standards for regulatory and pharmacovigilance purposes worldwide. The need to link these standards to other medication databases and medicinal product dictionaries for clinical use has been recognised. However, a concerted action to make this happen and to drive the business case for such costly implementations has not started yet. Most countries do recognise the cost of preventable medication errors and the contribution that decision support embedded in ePrescription or eDispensation systems at the point of care can have toward reducing this cost dramatically. Closed loop medication management is one of the key quality measures for hospitals and other healthcare provider organisations.

From a research and development perspective, the terms translational medicine and personalised medicine are being linked to the introduction of new medications and genetic markers that indicate a patient’s responsiveness to a particular treatment. Reducing the time it takes for new medication to travel from the laboratory bench to the bedside of the patient is key to saving lives. The required access to and understanding of complex information in order to decide whether a new drug will help an individual patient is holding back widespread use. There is a clear opportunity to streamline the trusted flow of data both in the clinical trial phase as well as in the market introduction and post-market surveillance phases.

The draft eStandards Roadmap for Common Identification of Medication zooms in on these issues, linking regulatory and pharmacovigilance initiatives to point of care benefits. A common drive for medication safety with leading roles for EMA, eHealth DSI, Patients, Pharmacists, Hospitals, and both Pharmaceutical and Health IT industry representatives would be welcomed to establish this connection and make sure it delivers the anticipated value to individuals, organisations, and to Member States. Part of the activities should be the development of an eStandards Roadmap for Common Identification of Medication that makes sure that medication data can be trusted and can flow from manufacturer to the point of care without any doubt about the medicinal product that is referenced and access to the latest information pertaining to the safe use of such medication.

Part of such a drive for medication safety would affect most other areas of eStandards and in particular, the International Patient Summary specification, making sure the identification of medication is handled in accordance with the proposed common identification schemes. Providing modern tools to
develop, distribute, implement, deploy and maintain the required eStandards for medication becomes essential when considering the impact such standards will have on the full range of eHealth applications, including mobile apps and decision support systems. Working together with industry will provide a broad basis for collaborative development of open tools for this purpose.

The full account of applying the methodology appear in the full roadmap document available from eStandards-project.eu website.
4. Taking the eStandards Roadmap Forward

The eStandards roadmap comes shortly after the midterm review of the digital single market to elaborate on the proposed actions for employing standards to facilitate large-scale eHealth deployment and adoption at lower cost. Digital transformation of health services promises the triple win, better quality healthcare at affordable cost with timely access, whilst boosting innovation and business growth.

Reasons for eStandards adoption

Adopting the eStandards approach that builds standards into the early stages of the user need and service design discussion, and keeps Standards Developing Organisations engaged every step of the way, will help unlock added-value for EU citizens, patients, researchers, and entrepreneurs. We are not there yet and limited, inconsistent, or incomplete adoption of eHealth standards is a significant contributing problem. According to Eurobarometer 460, the percentage of hospitals exchanging clinical care information about patients electronically with other healthcare organisations within the same country ranges from 33% to 39% and cross-border accounts only for 4% of this exchange. Only 9% of European hospitals offer their patients even partial access to their health records, even though this is required by EU level data protection legislation. Eurobarometer has also shown that 52% of citizens would welcome electronic access to their health records. It is encouraging that Member States work together in the eHealth DSI to create an infrastructure that ensures secure cross-border transfer of health records electronically and use of such records for safe care along with e-prescriptions to dispense medication abroad. In the end, veritable change is achieved when it addresses the needs of European citizens, as the major driver of digital health transformation, enabled by a renewed engagement with standardisation. eStandards can make this happen.

This is not to underestimate, however, the importance of and challenges in building momentum for eStandards at the operational level of healthcare provider organisations within Member States, including their vendors, and the citizens and workforce they serve. Coordinated action is needed to socialize the eStandards approach in the national and local entrepreneurial initiatives that aim to provide access to data for patients and to facilitate the exchange of health information across organizational boundaries. The ingredients for this action rest at the local level and need to be embraced by eHealth stakeholders including professional societies, patient advocacy groups, and national eHealth competency centres. Likewise, Standards Developing Organisations need to prepare for coordinated contribution to local eStandards roadmaps through their national member bodies and local collaboration across organisations. Outreach and education on the eStandards Roadmap Methodology at a national level is therefore crucial for the proposed approach to succeed. If the eStandards movement is to succeed, horizontal, grassroots, and systemic initiatives need to be orchestrated, through keystone projects that address the full eStandards life cycle in a start-up spirit.

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20Attitudes towards the impact of digitisation and automation on daily life, Eurobarometer 460, May 2017 ec.europa.eu/commfrontoffice/publicopinion/index.cfm/Survey/getSurveyDetail/instruments/SPECIAL/surveyKy/2160
Although the societal benefits of digital health innovation will predominantly be reaped at the individual health system level, this does not mean that eStandards can be developed in isolation. Apart from the fact that developing and deploying eStandards in itself is a costly exercise, being able to take advantage of the Digital Single Market for eHealth solutions and services will benefit all health systems across Europe. In addition, eStandards strengthen the position of Europe in the global Health IT marketplace, providing a broader “local market” for SMEs and thus enabling them to develop into truly global players. Hence the need for a coordinated eStandards effort, stimulated by true Member State cooperation at the level of the eHealth DSI, combined with innovative service driven initiatives that address the needs of the European citizens.

An even stronger case can be made for Europe as a highly competitive health data hub. High-performance computing through big data for health and advanced data analytics in areas of development of medicines, early detection of emerging infectious diseases and management of chronic disease can benefit from structured data and reliable terminologies that are seamlessly used. However, such visionary approaches towards data quality require radical thinking about digital health standards illustrated also by the PROGRESSIVE project, which brings together standardisation initiatives from eHealth, Ambient Assisted Living, and Active and Healthy Ageing.

Following the midterm review\(^2\), the digital single market priorities for health and care can be summarized as the ambition to:

(a) Give citizens better access to their health data everywhere in the EU;

(b) Connect and share health data for research, faster diagnosis, and better health outcomes;

(c) Use digital services for citizen empowerment and person-centered care.

These priorities shape our expectations for availability of tools and services for European citizens and we are making progress. With eHealth DSI operational in 2020, European citizens should be able to access and transfer their electronic health record, in full confidence of respect for privacy, when receiving healthcare anywhere in Europe.

European Reference Networks for Rare Diseases, pooling medical expertise and data for faster diagnosis and treatment of rare and complex diseases, are positioned to advance research, accelerate development of medicines and medical devices, and stimulate innovative healthcare solutions such as telemedicine and mobile health applications. Imagine the possibilities where patients are activated.

Finally, digital health tools fully respecting data protection rules can help improve health and support sustainability and resilience of healthcare systems.

eStandards established as infrastructure for innovation, catalyse patient interaction with the health team, to support preventive care, healthy lifestyles and citizen empowerment, as well as quality and patient-centred care through better understanding of the outcomes of healthcare systems. Again, these initiatives need to be built from the ground up, guided by a common vision of how eStandards contribute to common goals in health management and healthcare delivery as well as a common infrastructure that provides an additional motivation for a trusted flow of health data across borders.

Recommendations

The following recommendations and concrete follow-up actions to the eStandards project have been identified, including:

1. Identify keystone projects at a grass-roots level within the Member States that take into account the full range of stakeholders across the eStandards Compass, directly involving citizens as patients and informal caregivers. Such projects will benefit from engaging with the full eStandards life cycle in an entrepreneurial start-up spirit, thus building momentum for eStandards at the operational level of healthcare provider organisations within Member States, including their vendors, and the citizens and workforce they serve.

2. Support these keystone projects in their use of eStandards through a network of expertise, building upon local collaboration across the national member bodies of Standards Developing Organisations and national eHealth competency centres. Such collaboration will provide a coordinated contribution to local eStandards roadmaps for the benefit of local, regional and European investment.

3. Invest in outreach and education on the eStandards Roadmap Methodology at a national level to strengthen the network of expertise and its linkage to European and global eStandards communities.

4. Consider the role of a European platform representing the eHealth Standards Developing Organisations and national eHealth competency centres, as identified by the eHealth Network. Such a platform could well play a coordinating role as a guardian of the roadmap components and specific standardised artefacts that are identified across the various eStandards Roadmaps for particular focus areas in health management and healthcare delivery across Europe.

Engaging innovative vendors and users of eHealth solutions, will help them build upon an existing basis of eStandards in action. This can be supported by the adoption of the eStandards Roadmap approach for the actual delivery of eHealth services. In order to make this happen, the following concrete topics are suggested for further investigation:

1. Join forces between the different Patient Summary initiatives to consider the development of a joint eStandards roadmap for unplanned and emergency care.

2. Request all projects aimed at further development of integrated care and chronic disease management to establish an eStandards roadmap for their project. This is especially important since such projects typically aim to break down the traditional silos in healthcare delivery.

3. Establish an eStandards roadmap in close collaboration with the stakeholders of the Clinical Patient Management System for European Reference Networks for rare diseases.

4. Take a collaborative European approach toward medication safety as a corollary to both the eStandards and openMedicine projects, providing for eStandards based on EMA regulatory requirements, eHealth DSI ePrescription support, national pharmaceutical agencies and vendors of decision support systems for prescription and dispensing of medication.

It is our conviction that these actions will help create the necessary trust and flow of health data throughout the personal health network of the individual European citizen and will therefore realize the dream of Henk Bakker, to whom this roadmap is dedicated.
5. Full eStandards Roadmap

The eStandards roadmap for collaborative and sustainable standards development consists of the following parts:

- Core Document: The eStandards Roadmap
- Companion Document 1: The eStandards Roadmap Methodology
- Companion Document 2: The eStandards Roadmap Components

For full documentation on the eStandards project see:

www.estandards-project.eu
Deliverable description

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<th>D3.5: Roadmap for collaborative and sustainable standards development: Recommendations for a globally competitive Europe</th>
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<td>Publishable summary:</td>
<td>This deliverable describes the way forward for the development, deployment and refinement of eHealth standards that will support large-scale eHealth deployment in support of health maintenance and healthcare delivery in the digital age. Trust and flow of health data has the capacity to transform healthcare and is supported by eStandards, which are ‘live’ standards that are easily deployed in eHealth applications. Rather than providing a set course for Standards Developing Organisations to take, the eStandards Roadmap describes a process through which co-creation, governance and alignment (CGA) can be achieved across all stakeholders that are key to the success of large-scale eHealth deployment. The methodology for collaborative and sustainable roadmap creation, grounded in the CGA model, is outlined and applied to four focus areas that have a significant impact on European health systems: unplanned or emergency care, chronic disease management, rare disease networks and common identification of medicines. In all areas opportunities are identified to take the eStandards Roadmap work further.</td>
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Deliverable 3.5 consists of three parts:
1. This core document, comprising the roadmap and recommendations
2. A companion document describing the eStandards Roadmap Methodology
3. A companion document describing the eStandards Roadmap Components

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Editors: Robert Stegwee, Petra Wilson, Catherine Chronaki


Statement of originality
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