BUSINESS PLAN
CEN/TC 251
HEALTH INFORMATICS

www.ehealth-standards.eu

Standardise - Deliver - Innovate

EXECUTIVE SUMMARY

The COVID-19 pandemic has provided an unprecedented boost to digital health initiatives. Pure necessity has seen tremendous growth in the actual uptake of telehealth solutions. In addition, the shortcomings in current models for health data sharing were laid bare, both in the individual care for patients, as well as from a public health surveillance perspective. The challenges to drive the implementation of digital health at scale are many, and CEN/TC 251 Health Informatics is ready to contribute from its current status as well-connected player both in the European and the global health informatics standards world. With a global market for digital health solutions, we continue to strive for global standards that fit the needs and the values of Europe. Adding to our past track record, we have seen considerable success with both the International Patient Summary standard and the technical specification for Quality and Reliability of Health and Wellness Apps.

Our mission is to contribute to the development and maintenance of health informatics standards that support high quality, safe, and efficient delivery of healthcare services in close collaboration between healthcare professionals and citizens. In our work we focus on the requirements of all European stakeholders and seek to make them globally applicable. To this end we formalise existing guidelines, specifications, and practices for personal health data capture, processing, and exchange. Thus, with our contribution, we provide for a global market, both for our healthcare institutions to procure their solutions, but also for our innovative digital health industry to expand their reach.

We need to attract the next generation of health informatics experts to remain a viable and vibrant community. This requires communication together with more visibility and endorsement of the standards work, but also a rethinking of the nature of health informatics standards and their development. A more agile and digital way of working and publishing will be explored, in close collaboration with our companion standards development organizations in health informatics. Engaging in actual implementation, understanding the relevance and shortcomings of our standards, and responding more quickly to changing requirements, whilst remaining a trusted source for market guidance, will be crucial to achieve this objective.

In support of the digital transformation of health and care in Europe, we are committed to transform the way in which health informatics standards are delivered and used across the globe.

1 BUSINESS ENVIRONMENT OF THE CEN/TC

1.1 Description of the Business Environment

1.1.1. The sector of interest

'Health informatics' is information engineering applied to the domain of health. The definition of 'health' we use stems from a concerted effort to renew the original WHO definition[1]. In this definition often quoted as "positive health"[2], health is defined as the ability to adapt and to self-manage in the face of social, physical, and emotional challenges. It retains the inclusive nature of the WHO definition, covering "physical, mental, and social well-being, not merely the absence of disease or infirmity", but recognizes that certain conditions are chronic in nature. It implicitly covers genomics, precision medicine and cultural/spiritual matters. This comprehensive scope also recognizes that diseases and other challenges do not respect borders and that solutions, therefore, must overcome any barrier that limits self-management or the delivery of necessary care.

Health informatics is at the intersection of information science, computer science, management and care professions and services. It deals with the resources, systems, devices, and methods required to optimise the acquisition, storage, retrieval, and use of information in health care. Health informatics tools include not only algorithms, computers, and technology, but also conceptual models, system architectures, clinical guidelines, quality metrics, formal medical terminologies, as well as clinical and genomic data representations and analytics related to big data.

Essentially, health informatics is concerned with the quality of healthcare data, and the processes and digital (innovative) technologies to capture, transform and present that data, to support and enhance the quality of healthcare delivery for the benefit of the individual and of society as a whole.

Whilst 'health informatics' is a recognized term in Europe, 'eHealth' is probably the most frequently used, with 'digital health' becoming popular as well. The term 'digital health' at least recognizes that digital technologies are rapidly converging with health and healthcare, with everyday living, and with society at large, to enhance the quality of healthcare delivery. The term is also inclusive and efficient in that 'information', 'communication' and 'computational' technologies are all considered to be an intrinsic part of the interconnected digital ecosystem, along with hardware and software solutions, and services.

The breadth of digital health is impacted also by the regulation on the European Health Data Space (EHDS)[3], proposed in May 2022. The objective is "to improve access to and control by natural persons over their personal electronic health data in the context of healthcare (primary use of electronic health data), as well as for other purposes that would benefit the society such as research,

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[1] https://www.bmj.com/content/343/bmj.d4163

[2] https://www.iph.nl/en/positive-health/what-is-it/

[3] https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974-cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC_1&format=PDF

innovation, policy-making, patient safety, personalised medicine, official statistics or regulatory activities (secondary use of electronic health data)." The intent of the proposed regulation is to foster innovation of digital health services. Thus, the health informatics standards that CEN/TC 251 develops and maintains should cover four main areas, as depicted in the illustration below.

Source: ESMT Berlin | acatech | Technologie, Strategie und Leadership

1.1.2 Background

CEN/TC 251 holds a strategic and responsible position in the standards arena in the EU and affiliated countries, including Norway, the United Kingdom and Switzerland[4]. This position is widely recognized and respected by its members, stakeholders, as well as other Standards Development Organizations (SDOs):

- Implementing European Commission actions to meet the EU ambitions, while at the same time recognizing new European standardisation requirements and contributing to the EU standardisation strategy;
- Interacting with the national members and their standardisation bodies collecting, sharing, and harmonizing standards, needs and contributions;
- Collaboration on a European and international level with the relevant stakeholders and the SDOs, coordinating initiatives and starting new ones in the global health informatics standards arena;
- Ensuring fair competition conditions and a high level of protection of personal health data, together with the free flow of knowledge and experience in the health informatics industry and the health systems across Europe.

The COVID-19 pandemic has acted as an (unexpected) disruptive agent in the acceleration towards the required digital transformation of the healthcare sector. The pandemic highlighted the need to accelerate the use of innovative technologies and methodologies in the realisation and provision of health services, both within countries as well as across borders.

The European Union has reacted strongly to the pandemic, through various initiatives. As reported on the NextGenerationEU website, its actions represent more than "just" a recovery plan, it is a once-in-a-lifetime opportunity to emerge stronger from the pandemic, transform our economies and

4 We will only mention these affiliated countries once; they are implicitly recognised when we mention Europe and/or EU in the remainder of this document.

societies, and design a Europe that works for everyone. A vision, a plan, and investments are envisaged: €806.9 billion to make Europe healthier, greener, and more digital.

Apart from the need for a strong recovery, the pandemic has made evident the need of an acceleration towards quality, covering a very broad-spectrum including health and wellness data, apps, digital tools, interoperability, etc. Many of these topics were already on the EU and member states' agenda. However, the need for commonly agreed quality validation and evaluation frameworks is now more clearly visible, as is the need for resilience to unpredictable events.

1.1.3 Description of the Business Environment

The actual business environment for the standards of CEN/TC 251 comprises small, medium, large, regional, or even national healthcare organisations, together with their healthcare professionals and patients, on the one hand, and several very large, often global, software producers and many small and medium-sized enterprises (SMEs) operating primarily either in domain niches or in geographic areas, on the other.

This disparate global market is mirrored within the CEN member states and presents a challenge, with mounting costs for healthcare organizations and health informatics vendors with limited potential for growth in their marketplace. Change is needed, even more so as we are moving towards the Digital Single Market, one of the European Commission's 10 political priorities. It aims to successfully implement EU's single market for the digital age moving from 28 national digital markets to a single one, and then to open up digital services to all citizens, strengthening European business competitiveness in the digital economy.

In other words, the Digital Single Market is a market characterized by ensuring the free movement of people, services and capital, and allowing individuals and businesses to seamlessly access and engage in online activities irrespective of their nationality or place of residence.

The European Commission is showing an unprecedented policy ambition that relates directly to this Digital Single Market for healthcare and health technology, notwithstanding the subsidiarity principle which clearly positions the delivery and regulation of healthcare services as national responsibilities of the member states. Relevant regulatory developments, which are closely monitored by CEN/TC251, include:

- The European Health Data Space (EHDS), with strong references to
    - The European Electronic Health Record Exchange Format (EEHRxF)
    - The need for certification of Electronic Health Record Systems (EHR-Ss)
    - The need for requirements and technical specifications for, among others, data quality and utility labelling
    - Quality labelling, initially applied to apps in the health and wellness sector, to be extended to other domains, such as generic wellness applications interacting with EHR-Ss, software as a medical device (SAMD), medical and consumer health devices, etc., with the major goal of facilitating safety, privacy, security, and interoperability
- The Artificial Intelligence Act, in which health is indicated as a high impact area, and references:
    - The availability of health data for the training of artificial intelligence algorithms through the European Health Data Space

- The establishment of an AI regulatory sandbox for the development of innovative AI systems in the area of, among others, public health, including disease prevention, control, and treatment.

EHDS is an important regulation to achieve improved interoperability between the primary health information systems and the applications that use health data, both in primary (cross-border) delivery of healthcare and in secondary (multi-centre) analysis, reporting and research. With respect to its forthcoming regulation, CEN/TC 251 has emphasized, and will continue to emphasize, the role of European standards, and especially those linked to international standards, in providing safety, security, and market competitiveness for digital health information systems and apps. European and international standards have been developed with direct input from the healthcare market itself and therefore have a large support base. The market for primary information systems and health and wellness apps is typically a global market, with key players from all over the world providing their products and services to healthcare provider organizations as well as to patients, citizens, and consumers. Incorporating the essential element of references to European standards would only strengthen the regulation, to put the words into actions and to provide safety, security and market competitiveness for information systems and apps in healthcare.

The continuously evolving landscape of our Business Environment is enriched with many new technological, organisational, and methodological topics, applied into various areas of healthcare, that are followed closely by CEN/TC 251, such as:

- Advanced data analysis techniques, including artificial intelligence agents and algorithms
- Privacy preserving and enhancing technologies, rooted in a privacy by design approach, including public key infrastructures, blockchain, non-fungible tokens, and (quantum) cryptography
- Public values, such as user experience, accessibility, ethics, sustainability, etc.

CEN/TC 251 looks specifically at the different supporting guidance and (financing) opportunities made available by the European Commission, to develop and implement its standards as part of an ecosystem of active partners, in line with the strategy of the European Commission:

- The 2030 Digital Compass: the European way for the Digital Decade[5]
- The annual EU work programme for European standardisation[6]
- Rolling plan for ICT standardisation[7]
- The programmes implemented by the European Health and Digital Executive Agency[8]
    - EU4Health[9]
    - Horizon Europe[10]
    - Digital Europe[11]

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5 https://eur-lex.europa.eu/resource.html?uri=cellar:12e835e2-81af-11eb-9ac9-01aa75ed71a1.0001.02/DOC_1&format=PDF

6 https://ec.europa.eu/docsroom/documents/48601

7 https://digital-strategy.ec.europa.eu/en/policies/rolling-plan-ict-standardisation

8 https://hadea.ec.europa.eu/index_en

9 https://hadea.ec.europa.eu/programmes/eu4health_en

10 https://hadea.ec.europa.eu/programmes/horizon-europe_en

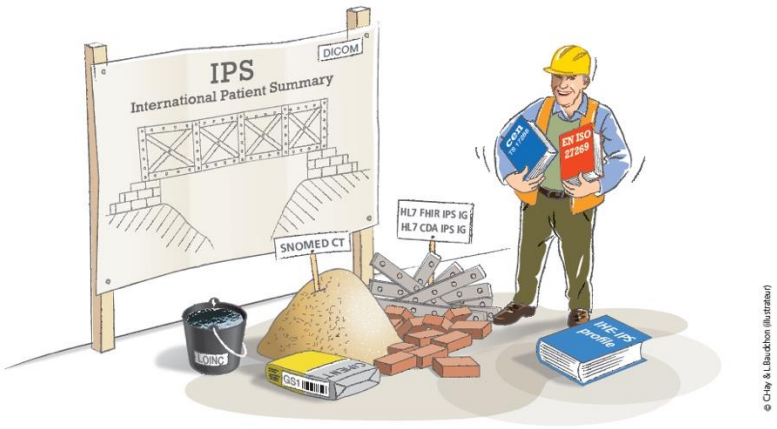
11 https://hadea.ec.europa.eu/programmes/digital-europe-programme_en

In reference to the EU Strategy on Standardisation[12] and the stated necessity to enhance European leadership in global standards, CEN/TC 251 will continue and strengthen its global position. Our global counterpart ISO/TC 215 Health Informatics has adopted many CEN/TC 251 standards, making the European input both a valuable contribution and facilitating the uptake of solutions that are relevant for, and often initiated in Europe. Two recent examples of such standards are:

- The International Patient Summary[13] – an initiative led by CEN/TC 251, funded by the European Commission, and now quoted by the G7 Countries as a standard to embrace for access to personal health data by their citizens
- The Quality and Reliability of Health and Wellness Apps[14] – another initiative led by CEN/TC 251, again funded by the European Commission, and adopted simultaneously by IEC and ISO as well.

Where possible the 'Vienna Agreement'[15] process is used to ensure that, for each subject matter area, only one standard is approved by ISO and CEN, and is adopted worldwide.

CEN/TC 251 plays an active role as one of the ten members (as of 2022) of the Joint Initiative Council for Global Health Informatics Standardization[16]. Part of the vision of the Joint Initiative Council (JIC) is to achieve widespread adoption and use of harmonized health informatics standards, where a singular set of standards is recognized as addressing each health business need. As a key achievement, the JIC has been instrumental in creating broad support for, coordination and visibility of the International Patient Summary set of standards and specifications[17].



12 https://ec.europa.eu/docsroom/documents/48598

13 https://standards.cencenelec.eu/dyn/www/f?p=CEN:110:0::::FSP_PROJECT,FSP_ORG_ID:74715,6232&cs=13F020852CA0536040D7F031E8E778759

14 https://standards.cencenelec.eu/dyn/www/f?p=CEN:110:0::::FSP_PROJECT,FSP_ORG_ID:66060,6232&cs=1D793D1609F2E391540DF6EEE8507EBEA

15 Vienna Agreement process: www.iso.org/va

16 http://jointinitiativecouncil.org/

17 https://international-patient-summary.net/

In terms of visibility, nearly 800 interested parties joined the JIC OpenForum sessions[18], from all regions of the world, and became more familiar with JIC's role and mission, that includes projects that can be accessed from JIC's dedicated page[19]. It is worth noting the JIC projects listed in such page include visibility to projects extremely relevant for and/or initiated by CEN/TC 251 in Europe.

1.2 Quantitative Indicators of the Business Environment

In 2019, the global digital health market was worth an estimated 175 billion US dollars. With an expected compound annual growth rate (CAGR) of almost 25 percent from 2019 to 2025, the digital health market should reach nearly 660 billion US dollars by 2025 (Statista Research Department, Jun 26, 2021[20]).

For example, over the last decade, investor funding in the digital health industry has increased significantly[21]. In 2020, over 21 billion US dollars was invested in the industry, compared to around one billion US dollars in 2010. Even before the COVID-19 pandemic in 2020[22], which sharply increased the need for digital health tools to be used, consumers' adoption of digital health had been steadily increasing[23]. In 2019, 42 percent of Americans reported using digital health tracking.

Due also to global resilience and recovery plans with respect to the COVID-19 pandemic, the telemedicine market is expected to drive the growth of the digital health market. Some experts believe this market can grow up to an expected value of 560 billion US dollars in 2027[24], from 41.63 billion US dollars in 2019. The global impact of COVID-19 has been unprecedented and staggering, with telemedicine witnessing a positive demand shock across all regions amid the pandemic. Based on this analysis, the global market would exhibit a stellar growth of 91.7% in 2020. The market is projected to grow from 79.79 billion US dollars in 2020 to 396.76 billion US dollars in 2027 at a CAGR of 25.8% in the 2020-2027 period. The high growth of telemedicine is due to the fact that it not only helps patients to connect with healthcare professionals remotely (especially the ageing and fragile), but it can also aid in reducing the total cost burden of healthcare. Physicians, hospitals, and regional/national healthcare services are looking forward to adopting digital health technologies in their practice, triggering the development of regulations and reimbursement policies revolving around telehealth, all requiring a huge number of policies, guidelines, quality criteria etc., that are subject of standardization activities.

An example of this need is the aforementioned standard for Quality and Reliability of Health and Wellness Apps, the development of which was strongly supported since it was required to provide a commonly agreed and accepted (European) framework for health and wellness apps in the COVID-19 era. A draft version of this standard has been made available by the European eHealth Network, through the Common EU Toolkit for Member States[25], to support the development of contact tracing and warning apps.

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18 http://www.jointinitiativecouncil.org/recordings/index.asp

19 http://www.jointinitiativecouncil.org/registry/index.asp

20 Statista Research Department: https://www.statista.com/aboutus/our-research-commitment

21 https://www.statista.com/statistics/388858/investor-funding-in-digital-health-industry/

22 https://www.statista.com/statistics/1133920/telemedicine-and-covid-19-impact-us/

23 https://www.statista.com/statistics/1102227/adoption-of-digital-health-tools-by-type-us-adults/

24 https://www.fortunebusinessinsights.com/industry-reports/telemedicine-market-101067

25 https://ec.europa.eu/health/document/download/01f83f72-4e21-4a34-90dd-ec0b0cc35c8b_en?filename=covid-19_apps_en.pdf

Getting back to our European Union landscape, a survey of European health professionals found that they believed the biggest digital health trend in the coming years will be the use of patient owned health data[26]. In general, most healthcare workers thought digital health prospects in their country would improve in the coming year[27]. However, the biggest challenge to implementing digital health changes efficiently and effectively in Europe is regarded to be funding and costs[28].

The considerations are aligned with the expectations of EU citizens, as described in the Digital Health and Care[29] infographic:

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

The impulse towards an accelerated digital transformation of healthcare must not underestimate the need for inclusive accessibility and proper user experience (UX). This impacts the way healthcare professionals and patients (or their families or informal caregivers) interact with digital tools aimed at providing better quality services. In fact, healthcare professionals (doctors and nurses alike) continue to bemoan the amount of time they spend doing administrative work "to satisfy the system". While things are slowly getting better, studies[30] demonstrate that clinicians' first-hand experiences need to be carefully reviewed to identify the possible benefits, costs, drivers, and barriers to implementation of an EHR-System. These considerations are valid in general for all digital tools, not only for the EHR-System. Both healthcare professionals and patients are end-users, so their perceptions and behaviours have an impact on how much or well the system is utilized. This leads to extended stakeholder requirements also in such fields for the development of norms, quality criteria and guidelines.

2 BENEFITS EXPECTED FROM THE WORK OF THE CEN/TC

As stated at the beginning of the Business Plan, CEN/TC 251 plays a strategic role in the standards arena. Its objective is to act as a hub receiving multiple inputs for standards' needs from multiple stakeholders. At the same time CEN/TC 251 initiates activities to provide EU-specific guidance, also outside of the EU-boundaries through bidirectional engagement with relevant stakeholders and international SDOs. Our engagement with JIC activities is aimed at influencing global standards, e.g., through the Vienna Agreement, and at the same time gathering relevant information from international initiatives. Both strive to strengthen the European position in the global marketplace of digital health solutions.

Looking forward, the expected benefits from the work of CEN/TC 251 include:

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26 https://www.statista.com/statistics/1010465/future-ehealth-trends-in-europe/

27 https://www.statista.com/statistics/1010683/levels-of-optimism-in-ehealth-sector-europe-by-country/

28 https://www.statista.com/statistics/1010439/challenges-for-ehealth-providers-europe/

29 ec.europa.eu/digital-single-market/en/news/infographic-digital-health-and-care-eu

30 See e.g., https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8902175/

- Increased quality and interoperability of digital health applications to support high quality, safe, and efficient delivery of healthcare services in close collaboration between healthcare professionals and citizens.
- Engagement in and European influence on global standards:
    - through activities in the JIC and the Vienna Agreement; a key example is the development of the International Patient Summary standard, initially developed as an EN, which has now been adopted through a fast-track process by ISO/TC 215 and will be maintained jointly under Vienna Agreement
    - establishing further partnerships and collaborations also outside of the EU boundaries, remaining loyal to EU policy and agreements, thus strengthening the Digital Single Market by building on existing work, and if necessary, producing new work to meet emergent requirements
- Provision of specific European guidance through its standards:
    - CEN/TC 251 offers a unique channel to produce formal standards which support the EU policies and stakeholder requirements in the health informatics arena
    - CEN/TC 251 can formalise EU guidelines and best practices, turning them into international standards while remaining faithful to the European requirements
- Visibility of all EU activities, initiatives, needs, regulations & acts, standards, etc.: CEN/TC 251 gives Europe a united voice to talk to other SDOs and standardization fora.
- Provide tools for the National Member Bodies (NMBs) of CEN/TC 251, while observing their local initiatives and offering proactive support
- Proactively follow EU R&D projects identifying suitable candidate topics for standardisation activities
- By applying topics of interest to various areas of healthcare, topics such as quality labelling, user experience, accessibility, AI, privacy by design, blockchain, and others as mentioned above, CEN/TC 251 expects:
    - to strengthen its relationships to universities and EU SMEs, thus attracting a younger ‘next generation’ audience that is the actual rider and driver of the digital transformation, giving further momentum (and enthusiasm) to EU standardization activities
    - raise the number of commercial organisations, user organisations, and NMBs engaged in its work.

Just to provide a more concrete indication of the expected benefits, annex 1 contains a list of standards being drafted within CEN/TC 251 Health Informatics (status as of October 2022).

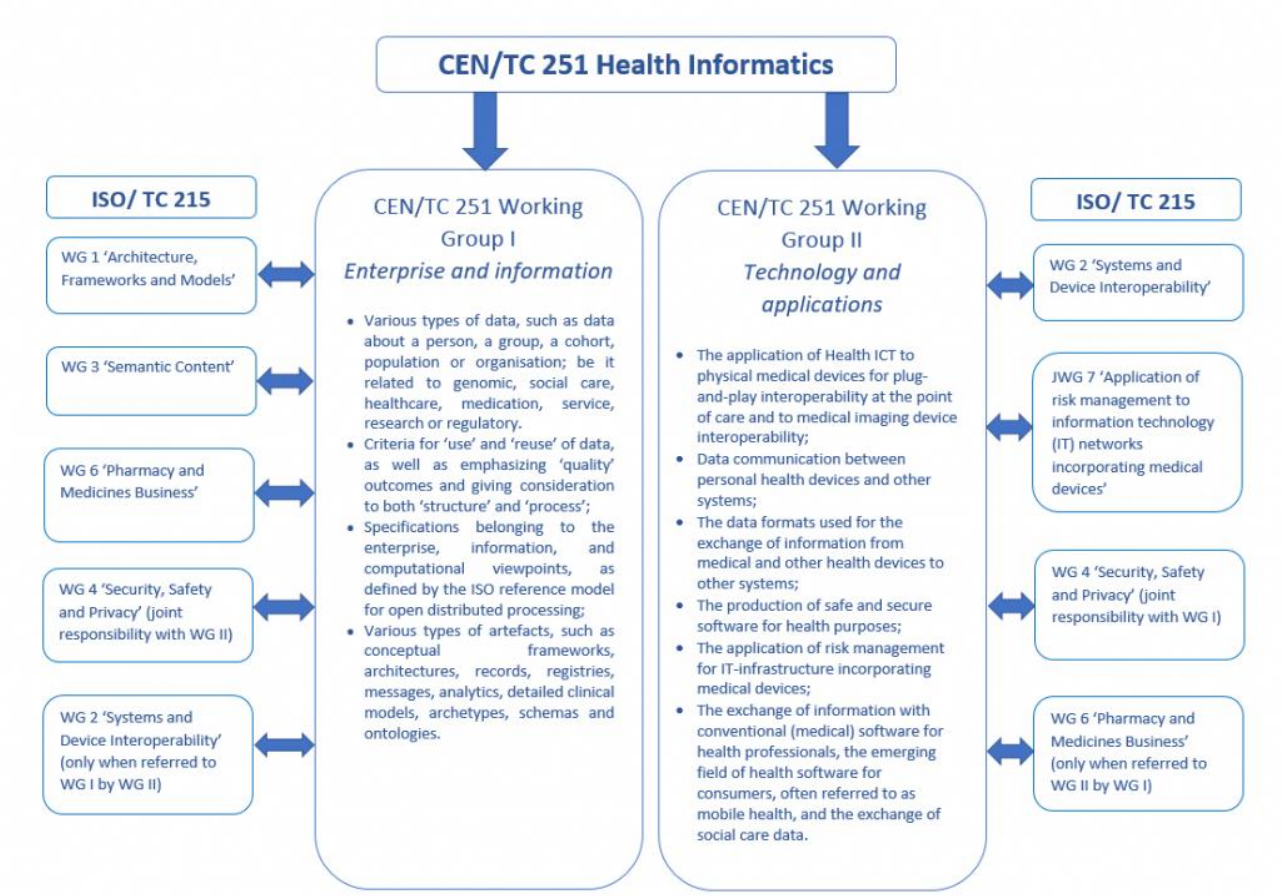
3 PARTICIPATION IN THE CEN/TC

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

Out of the 34 national members in CEN, 26 have designated one or more Committee members of CEN/TC 251, 4 not being members of the EU. Just one member has only appointed a Document

monitor to the work of CEN/TC 251, without active participation in the work of the TC. In addition, 5 liaison organizations, including one EU funded project, are engaged as Committee observers in our work, as well as a number of counsellors from the European Commission, in particular from DG CNECT[31] and DG SANTE[32].

The overall organisation and work programme of CEN/TC 251 is illustrated in the following figure. This highlights once more the importance of collaboration with our global counterpart ISO/TC 215 Health Informatics. Participation and coordination are achieved through both WGs and with the Management Team of CEN/TC 251. This management team consists of the chair, vice-chair, secretary, and convenors of WGI and WGII. Because of the importance of the work of ISO/TC 215 WG6 (Pharmacy and Medicines Business) for Europe, we are happy to be able to also include the (European) convenor of WG6 in our MT meetings.



Participation in WGI and WGII is focused mostly on coordinating and discussing the work going on in ISO/TC 215, with an occasional work item focused solely on the European stakeholders. The composition of both WGs is included in Annex 2, including the backgrounds of the participating experts..

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31 https://ec.europa.eu/info/departments/communications-networks-content-and-technology_en

32 https://ec.europa.eu/info/departments/health-and-food-safety_en

CEN/TC 251 is actively engaged with many other standards development organisations. As mentioned before, CEN/TC 251 is (founding) member of the Joint Initiative Council (JIC) for Global Health Informatics Standardization. The JIC has an active and growing membership, including ISO/TC 215, HL7 International, IHE International, SNOMED International, DICOM and GS1, just to name but six. Within Europe, close collaboration has been established with HL7 Europe, IHE Europe, and SNOMED International. CEN/TC 251 also interacts with other SDOs, consortia, and fora to coordinate its work with other organisations that have similar goals.

CEN/TC 251 has established working relationships with, among others:

1. CENELEC through a Joint Technical Committee on Medical Devices (CEN/CLC JTC 3)
2. European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries (COCIR)
3. European Commission and its associated policy, research, and deployment projects.

In addition, CEN/TC 251 has played an active role in the European eHealth Stakeholder Group[33] since its establishment and will remain to do so. It is a rich network to interact with various industry, professional, and consumer organisations on the topic of digital health.
It is evident, however, that more NMBs, commercial organisations and user organisations could be engaged proactively in the work of CEN/TC 251. This has been identified as a weakness of the TC that is addressed by its current initiatives and strategic vision.

4 OBJECTIVES OF THE CEN/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

4.1 Defined objectives of the CEN/TC

CEN/TC 251's first objective is to proactively act on the need for Health Informatics standards and specifications to promote EU policies, regulations, and guidelines, and making sure these are always on the tables of relevant European and international stakeholders, as follows:

- focus on the healthcare domain requirements of the European Union and the Digital Single Market and seek to turn them into globally applicable standards
- formalise EU generated guidelines, create useful and usable frameworks to establish leading practice
- deliver relevant standards for regulation and research through participation in EU projects and initiatives.

CEN/TC 251's second objective is to become a more agile SDO (attracting more experts), finding better ways to engage and influence, and at the same time learn from, different stakeholder groups, expedite processes and establish relevant feedback mechanisms.

In short, the keywords that best describe CEN/TC 251's objectives are:

[33] https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&do=groupDetail.groupDetail&groupID=2769

1. **Awareness** of and within relevant digital health initiatives, where the need for health informatics standards is imminent
2. **Focus** on relevant EU driven topics in the digital transformation of health and care
3. **Launch** new and relevant work items, identifying the appropriate standards arena (European and/or global), making sure that EU values are always taken on board and that EU experts are engaged on the topics where they are needed and can proactively contribute
4. **Resource** key initiatives and work items with the appropriate experts, both from CEN/TC 251 and associated SDOs, and seek financial support where needed, through the various funding mechanisms available within the EU
5. **Participate** in the development, review, and implementation of relevant EU policies, regulations, joint actions, and projects, that may identify and answer the need for health informatics standards
6. **Attract** more active membership to EU (participation in) standardisation activities
7. **Provide** an active knowledge sharing community to NMBs to strengthen their local presence and network.

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

Several strategies are planned for reaching the objectives stated in the previous section. Such strategies have been also identified through the analyses of factors affecting completion:

- **Demonstrating relevance**: as an example, we give here the relevance of CEN/TC 251's involvement in quality labelling: the COVID-19 pandemic has demonstrated that it is possible to be resilient to emergency and critical situations, also by the quick delivery of digital tools. However, the effective and common evaluation and quality labelling through commonly accepted and standardised quality criteria frameworks of the quality of the digital tools – at the EU and member state levels – is fundamental to guarantee the quality of the response to such critical situations is
- **Fighting ignorance:** too often stakeholders demonstrate a lack of awareness of and familiarity with the work of CEN/TC 251 and the value it could bring to their endeavours. Active communication through social media and personal networking is promoted to overcome this perceived ignorance, also enabling the identification of mismatches between our standards and the real-world requirements of our stakeholders. In addition, we have invested in a topical website on the International Patient Summary, addressing the needs of our stakeholders from the combined efforts of the participating SDOs, rather than from an individual SDO perspective.
- **Attracting experts and resources**: in order to truly engage in the digital transformation, it is crucial that the "next generation" of experts, the digital natives, get involved in our work and reshape it to the needs of the future generations of developers and users of digital health. In addition, true to our vision of the health informatics standards development life cycle, discussed in more detail below, we need to stay engaged with the implementation of our standards to facilitate the revision and extension in a timely manner, responsive to the needs of our users. This requires a concerted effort with our NMBs to communicate and reach out to those that are actively engaged in the study, preparation and implementation of digital health in real life.

CEN/TC 251 has an excellent record of participation in EU projects and intends to continue to do so. Just as an example, in the spring of 2022 CEN/TC 251 has participated in the preparation of a

response to an EU CSA call on a pan-European ecosystem to promote the use of the European Electronic Health Record exchange Format (EEHRxF). Where it is not present as a TC, our experts bring EU knowledge, expertise, and requirements to the projects. To meet our objectives, such participation must continue (and is continuing). The depth of such participation must be strengthened in order to resource its work.

As a policy, CEN/TC 251 will regularly invite participants of EU projects to TC meetings or ad-hoc workshops to share experiences and initiate, plan, and verify standardisation work items. We are also considering further use of an internal CEN/TC 251 Review Group for EU projects that CEN/TC 251 and our experts participate in. Such a Review Group was first set up for the X-eHealth project and its operation will be evaluated to inform future use of this instrument.

In addition, in order to increase awareness, harmonisation, and receptiveness, CEN/TC 251 invites NMBs to TCs and workshops to present relevant national initiatives, to provide advice and to initiate, where and when possible, new items within our work program, where indicated.

The overall intent is to ensure that policymakers, stakeholders, and digitals actors consider and recognise our ability to mobilize the required technical expertise in productive collaborations. This is especially useful when bringing together different (global) SDOs to coordinate their standards development toward a working solution in the digital transformation of health and care. As healthcare providers and professionals put considerable effort into the internal restructuring of their Electronic Health Record Systems to enable, for instance, the exchange of meaningful patient summaries, both nationally and cross-border, CEN/TC 251 has taken the initiative to create coordinated standards and specifications for the International Patient Summary across five participating SDOs. Our healthcare providers and professionals, as well as the software vendors that serve them, are much better off when European and global recognition of a common set of coordinated standards is achieved.[34]

CEN/TC 251, in its strategic feedback on the proposed regulation on the European Health Data Space, has emphasized, and will continue to emphasize, the role of European standards, and especially those linked to international standards, in providing safety, security, and market competitiveness for eHealth information systems and apps[35]. One crucial reason is that the development of standards for healthcare data in the EU does not always take place through the instruments of the European Standards framework, rather through a parallel strategy of Horizon Europe project grants and other Commission funding instruments[36]. However, there is a lack of resources and processes necessary to assure both current and future incorporation of such project outcomes in the (global) standards and specifications that govern the market. We therefore will engage with our stakeholders on two different pathways in parallel:

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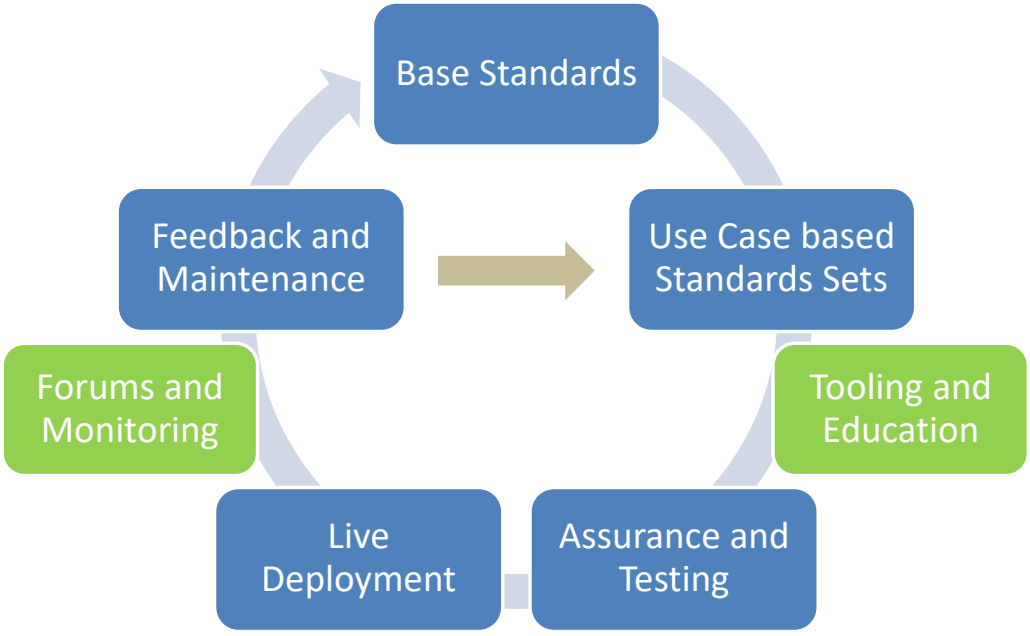
34 See also the 2015 *e*Standards deliverable "The case for formal standardization in large-scale eHealth deployment", to which CEN/TC 251 contributed substantially.

35 CEN and global standards (e.g., EN ISO 23903 Health informatics – Interoperability Reference Architecture) demonstrate that sharing data together with the knowledge behind the data enables/facilitates full interoperability, while this is much more difficult to obtain in a data space where the knowledge behind the data is missing. See also https://www.frontiersin.org/articles/10.3389/fmed.2022.802487/full

36 For example, X-eHealth EU Project has been financed by DG CNECT as CSA, whereby a consortium has been asked to develop the standards. These projects typically include representation from IHE Europe, HL7 Europe, as well as NEN on behalf of CEN/TC 251, and a whole range of European governments and other actors.

1. advocate for the effective use of the standardization process in the EHDS Regulation, either through harmonised standards, formal standards requests, or through standardisation projects such as the International Patient Summary and the Quality and Reliability of Health and Wellness Apps
2. we work on and propose a formalised way to coordinate the work between EU projects and the regular standards work, building upon the experiences coming from the UNICOM[37] and X-eHealth[38], incorporating such practices in all newly funded projects that aim at furthering the development of EHDS specifications.

It is the explicit strategy of CEN/TC 251 to engage with other SDOs and the stakeholders testing and implementing the standards to address their needs. We are convinced that we need to close the loop in the Health Informatics Standards Development Life Cycle, to remain relevant, to fight ignorance and to attract experts and resources to continue our work. To this end, we encourage active engagement with industry, researchers and academic stakeholders and find ways to give them more opportunity to be involved in our work items. In addition, we will engage in finding new ways to reach out to consumer/clinical/citizen groups as the ultimate beneficiaries of our work.



4.3 Environmental aspects

The standards products of CEN/TC 251 have no direct impact on environmental sustainability matters. However, the standards' work envisages usage of innovative technologies, procedures, and methodologies with the scope of bettering and making more efficient the provision and

37 https://unicom-project.eu/
38 https://www.x-ehealth.eu/

deployment of quality healthcare services deployed (e.g., in telemedicine, home based care, better public health; improved continuity of care; greater efficiency and effectiveness measures, indicators etc.), including their impact on sustainability.

It would still be possible to imply indirect impact by reduction of materials usage where the standards are deployed.

The working practice of CEN/TC 251, particularly at the task-group level, has been to reduce in recent years the negative environmental sustainability impact of its standards production activity by increasing the use of telephone and web conferencing technologies to hold meetings. This is a trend that has been further professionalized during the COVID-19 pandemic and that we expect to continue for both environmental and economic reasons.

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

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

In previous sections we have alluded to some specific factors that could negatively impact the completion or business community acceptance and use of the CEN committee's standards. They are addressed by specific strategies described in the previous chapter.

The key factors affecting our work are summarized here for the convenience of the reader:

- **Relevance**:
  - Topics at the EU level are often not recognized as relevant to national or local implementation efforts
- **Ignorance**:
  - Many are not aware of the initiatives carried out by CEN/TC 251
  - CEN/TC 251 needs to expand its participation/dissemination to stakeholders' tables to intervene with actions when the situation requires it
- **Availability of experts/resources**:
  - the "next generation" is not involved in standardisation
  - volunteer experts are hard to find, as the work is not well connected to their daily work life
  - standards in ICT are often perceived to be free, so funding for standards work is a constant issue

In our previous business plan (2019-2022) we described these factors in more detail, which we still feel are affecting our work.

1. **Policymakers'** uncertainty about standardization and their lack of engagement with CEN/TC 251 to support European objectives within the international market. Several initiatives carried out in the past, like Concurrent Use[39], and in the present[40], like Quality Labelling and the UNICOM project, have helped to explain our role, products, and benefits. On one hand, educational material that really makes our results and benefits known to a wider audience, including policymakers, is urgently needed, while on the other, CEN/TC 251 needs to strengthen its collaboration/participation with relevant stakeholders to proactively support and contribute properly to initiatives.

2. **Acceptance, adoption, and recognition of the CEN/TC activities and work** will rely on active acknowledgement of our contribution to real-life solutions, as well as recognizing the status of proven standards in health informatics. For instance, the International Patient Summary is currently endorsed by both the G7 group of countries, as well as by the Global Digital Health Partnership (GDHP[41]). The European Commission should consider actively promoting the International Patient Summary set of standards as a welcome development in the evolution of MyHealth@EU, including active engagement with the communities maintaining the CEN/ISO, HL7 and IHE standards and specifications that provide the basis for it. The project-driven approach to health data standards has also limited the visibility and acceptance of global standards, especially when the participation of SDOs depends on the consortium that is awarded the work. Having a wide variety of EU projects in digital health requires strong direction in the use of standards to maintain confidence and to foster sustainable standards-based solutions.

3. **Expert resources are not sufficiently available**, also due to lack of stakeholder support. This is a broader version of factor 1 above. However, as this area is multi-disciplinary in nature with many beneficiaries, the range of stakeholders becomes difficult to cover fully. There are a variety of reasons for this: competition from other SDOs; the lack of involvement of (inter)national eHealth competence centres in the more strategic aspects of standardization; the difficulty of providing compelling value propositions in the absence of suitable feedback mechanisms. In competing for scarce and valuable resources, the CEN (and ISO) business model for secretariat and expert involvement are not convincing. Particularly SMEs find involvement punitive. When specific expertise for a project is lacking, this could affect the project's development as well as the credibility of the resulting standard in the business community. Not to mention the need for the involvement of the "next generation" in standardisation activities.

4. **Shortage of funding** for participation on an international basis and at the regional level will damage both influence and output and reduce the EU's lead in this fast-moving domain. Much funding for digital health is being made available through the programmes like EU4Health, Horizon Europe, and Digital Europe, but we still have to find ways in which to make sure these funds can also be directed toward the structural standards work.

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39 https://contsys.org/page/CENConUse

40 https://www.ehealth-standards.eu/projects/

41 https://gdhp.health

5. **Lack of knowledge about how standards are used, where they are used, and their impact and value across Europe**. This point has a reverse issue: where and when standards could have been used but because of “ignorance” or other reasons they were neglected. It would be beneficial to have and maintain an accurate overview of what standards (organizations in) the member states are really using. Standards must not be judged just as SDO outputs but positioned in a framework for assessing longer-term outcomes.

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

Annex 1 Extract from the list of standards being delivered by CEN/TC 251, as of October 2022[42]

Project	Title
CEN ISO/prTS 20440 rev	Health informatics - Identification of medicinal products - Implementation guide for ISO 11239 data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging
EN ISO 13119:2022	Health informatics - Clinical knowledge resources - Metadata (ISO/DIS 13119:2021)
EN ISO 13131:2022	Health informatics - Telehealth services - Quality planning guidelines (ISO 13131:2021)
prCEN ISO/TS 14265 rev	Health Informatics - Classification of purposes for processing personal health information
prCEN ISO/TS 14441 rev	Health informatics - Security and privacy requirements of EHR systems for use in conformity assessment
prCEN ISO/TS 17251 rev	Health informatics - Business requirements for a syntax to exchange structured dose information for medicinal products
prCEN ISO/TS 19293 rev	Health informatics — Requirements for a record of a dispense of a medicinal product
prCEN ISO/TS 19844 rev	Health informatics - Identification of medicinal products (IDMP) - Implementation guidelines for ISO 11238 for data elements and structures for the unique identification and exchange of regulated information on substances
prCEN ISO/TS 23261	Requirements for accessing digital medicinal products information by using the existing data carrier
prCEN ISO/TS 5499	Clinical Particulars-Core Principles for the Harmonisation of Indications Terms and Identifiers
prCEN ISO/TS 6476	Health Informatics -- Logical Model for the Identification of Medicinal Products for ISO 11615
prEN ISO 10781 rev	Health Informatics — HL7 Electronic Health Records-System Functional Model, Release 2.1 (EHR FM)
prEN ISO 11073-10419 rev	Health informatics - Personal health device communication - Part 10419: Device specialization - Insulin pump
prEN ISO 11239	Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging (ISO/DIS 11239:2022)
prEN ISO 13940 rev	Health informatics - System of concepts to support continuity of care
prEN ISO 17117-1	Health informatics — Terminological resources — Part 1: Characteristics
prEN ISO 17523 rev	Health informatics — Requirements for electronic prescriptions
prEN ISO 18104 rev	Health informatics - Categorial structures for representation of nursing diagnoses and nursing actions in terminological systems
prEN ISO 21549-5 rev	Health informatics - Patient healthcard data - Part 5: Identification data
prEN ISO 27269 rev	Health informatics — International patient summary

42 The full CEN/TC 251 work programme can be found here: https://www.ehealth-standards.eu/programme/

prEN ISO 27799 rev	Health informatics - Information security management in health using ISO/IEC 27002
prEN ISO/IEEE 11073-10404	Health informatics - Device interoperability - Part 10404: Personal health device communication - Device specialization - Pulse oximeter (ISO/IEEE/FDIS 11073-10404:2022)
prEN ISO/IEEE 11073-10407	Health informatics - Device interoperability - Part 10407: Personal health device communication - Device specialization - Blood pressure monitor (ISO/IEEE/FDIS 11073-10407:2022)
prEN ISO/IEEE 11073-10408	Health informatics - Device interoperability - Part 10408: Personal health device communication - Device specialization - Thermometer (ISO/IEEE/FDIS 11073-10408:2022)
prEN ISO/IEEE 11073-10420	Health informatics - Device interoperability - Part 10420: Personal health device communication - Device specialization - Body composition analyzer (ISO/IEEE/FDIS 11073-10420:2022)
prEN ISO/IEEE 11073-20601	Health informatics - Device interoperability - Part 20601: Personal health device communication - Application profile - Optimized exchange protocol (ISO/IEEE/FDIS 11073-20601:2022)
prEN ISO/IEEEE 11073-10415	Health informatics - Device interoperability - Part 10415: Personal health device communication - Device specialization - Weighing scale (ISO/IEEE/FDIS 11073-10415:2022)
(WI=00251355)	Health informatics -- Terminological resources -- Part 2: Capability

Annex 2 CEN/TC 251 WG participating countries and background of experts

WGI

Country	Role	Stakeholder category
Germany	Convenor	-
The Netherlands	Secretariat / Committee member	-
France	Committee member	-
Austria	Committee member	SME / Industry and Commerce/ Academic and research bodies
Bulgaria	Committee member	-
United Kingdom	Committee member	Industry and Commerce
Germany	Committee member	Academic and research bodies/ Industry and Commerce
Denmark	Committee member	-
Portugal	Committee member	-
Ireland	Committee member	-
Poland	Committee member	-
Finland	Committee member	Government
Sweden	Committee member	-
Slovenia	Committee member	-
Norway	Committee member	-
Spain	Committee member	-
Italy	Committee member	-
HL7	Committee member	-
EN 13606	Committee member	Liaison Organisation

WGII

Country	**Role**	**Stakeholder category**
Finland	**Convenor and secretariat**	**-**
Austria	**Committee member**	**SME / Industry and Commerce/ Academic and research bodies**
France	**Committee member**	**-**
Bulgaria	**Committee member**	**-**
United Kingdom	**Committee member**	**Industry and Commerce**
Germany	**Committee member**	**Academic and research bodies/ Industry and Commerce**
Denmark	**Committee member**	**-**
Portugal	**Committee member**	**-**
Belgium	**Committee member**	**-**
The Netherlands	**Committee member**	**Industry and Commerce**
Ireland	**Committee member**	**-**
Poland	**Committee member**	**-**
Sweden	**Committee member**	**-**
Norway	**Committee member**	**-**
Spain	**Committee member**	**-**
Italy	**Committee member**	**Government**
HL7	**Committee member**	**-**