Health Informatics TC251

A newsletter from CEN TC251

The value proposition is to deliver de jure, quality interoperability standards for health within Europe.

This newsletter is a direct result of our strategy meeting with our National Member Bodies (NMB). The world is changing, and we wish to change with it. The new TC251 strategy provides us with an opportunity to move forward with the views of our users directing our way. We were told that we needed to be more visible, and to present what we have done, and what we do, in ways that people can easily grasp and use for their business. If in the past our marketing has been bad, in the future we need to change not only its style but also the nature of what is marketed. Our emphasis will now move away from the sole development of standards to the delivery of these standards. This still includes development but it entails a much more customer focused approach. We do not underestimate the scope of this challenge. This newsletter is a small step towards realising our new strategy as the TC begins to present and act differently. We hope you like it of course, but we welcome your reactions so that we can use them to improve the way we work in future.

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The TC251 Strategy

To be fit for purpose the TC251 standards must meet your requirements and therefore the community must show that they can be successfully implemented. The adaptation, profiling and adoption of interoperability standards should above all be relevant to the domain. TC251 is committed to delivering consensus-based output that provides the opportunity for all member states to engage throughout the standardisation life-cycle, knowing that this will provide quality end-products with a wider market.

➢ The 'Health' in 'Health Informatics'

Health and Social Care is already a single domain in many European countries and still others aspire to making it so in the future.

The World Health Organisation published a definition of 'health' in 1948, which remains unchanged to this day. They define health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."

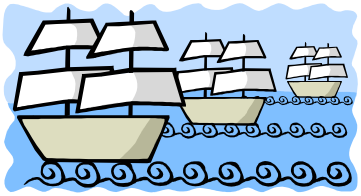
When CEN TC251 defines itself as the European Committee for Standardisation of Health Informatics (HI), it fully embraces this aspiration and vision for health in our region.

➢ CENtral to Europe + the World-wide HI Standards Community

CEN TC251 engages with most if not all of the Standards Development Organisations (SDOs) in our field. It was a founding member of the Joint Initiative Council (JIC) alongside HL7 and ISO. This important Council has now expanded to include IHTSDO (terminology), CDISC (Clinical Research) and GS1 (Identification). CEN TC251 has successfully worked with the European (EMA) and International regulators (ICH) for medicinal products. It is currently working with IHE in project work and with new consortia such as the clinical information modelling initiative (CIMI). The combined efforts of these organisations are expected to deliver the set of standards that are needed for true interoperability of health information systems. For more information on JIC see http://www.jointinitiativecouncil.org/

➢ CEN TC251: Standards Delivery Organisation for Interoperability

TC251 is moving to embrace the idea of 'delivering' HI standards, not just developing them. Interoperability is what this TC was created for back in 1990 and what it is all about over two decades later. But Interoperability in its widest sense includes meaningful interaction and communication between people as well as systems, and the CEN TC251 products in the past have not been as customer-friendly as they might have been. We intend to do better.



TC251 Flag-ships Update

From the start, the TC has developed standards that frame the way technology can support healthcare delivery. Here is an update of some of our key standards:

Electronic Health Records come of age: 13606

The first ever EHR architecture was standardised in CEN TC251 as ENV 12265 in 1996. It is now better known as 13606. In 2012, the 4th revision is now underway as a joint initiative between CEN TC251 and ISO. The scope of 13606 is to remain unchanged; it is designed to exchange part or all of a health record between different manufacturer's systems, and to do so safely, without loss of meaning and without loss of any original context.

As requirements become clearer and specifications become more mature, it is intended that the new revision of 13606 will be harmonised with both CDA and openEHR. The explicit mandate to the project team is to remove the confusion currently present in the market place. Building upon the considerable implementation experience, the revision of all 5 parts is expected to use a workable subset of the ISO data types, and to provide a leaner solution.

Continuity of Care: ContSys

Information and data models are important as a means to formally present specifications. Often though, these efforts are fragmented and start mid-stream without an overarching context to make them compatible with each other. ContSys provides some of that context. It is a comprehensive system of concepts for continuity of care. It therefore provides a concept model (not a data model) and the necessary terminology to describe a significant part of the healthcare domain.

ContSys was originally a CEN standard, before expanding its horizons to the rest of the world, and becoming a joint initiative in ISO. It has already been trialled and implemented in a number of projects across Europe. This development activity makes sure that when it is published it will be fully implementable, and has a set of conformance criteria for validation. (See http://en.wikipedia.org/wiki/System_of_concepts_to_support_continuity_of_care). ContSys is of interest beyond Europe, gaining much attention world-wide. Canada and Australia, to name just two, are actively participating in its improvement as it goes towards its final ballot in ISO later this year. For more information see http://www.contsys.net/

Health Informatics Service Architecture: HISA

HISA too began its life in CEN and is now a full 3-part ISO standard. It fits in with the commercial world's need for workable enterprise architectures, but was developed specifically with the health care domain in mind. The TC251 architects are involved in underpinning the ISO initiative to provide capacity-based eHealth architecture for low and middle income countries at the national level. HISA 12967 is also providing the basis for a development of a new Technical Report in CEN TC251 that reviews the existing enterprise architectures, gathers good practice and considers the future application of such architectures at a more local level within the domain of health and social care. For more information see http://www.hisa-standard.org/

Detailed Clinical Modelling: DCM

Clinical information modelling has always been daunting. Everything seems to be connected together and inter-related when it comes to describing clinical aspects of a person's state. The way we tend to deal with complexity is to consider parts of the whole in detail but that strategy always presents questions of boundary definition, management, governance, and how such parts can be put together so as to make sense in a safe way and be meaningful in a broader context.

Detailed Clinical Models (DCM), like archetypes from 13606 and openEHR, templates and clinical statements from HL7, are concerned with such problems and build upon the idea of 2 level modelling for electronic health records that has been an intrinsic part of CEN TC251's approach from the beginning. DCM is the focus of the CEN and ISO work.

DCM has a growing implementation base, particularly in the Netherlands. It has passed its committee draft ballots in ISO at the May 2012 meeting in Vancouver and is going forward as a Technical Specification.

This type of specification permits a flexible way forward and enables greater buy-in from the international community as the specification matures. For more information about the uses of DCMs see http://detailedclinicalmodels.nl/home-en

Clinical Information Modelling Initiative: CIMI

CIMI is a consortium that both helps and challenges the traditional SDO path to creating a standard. It attempts to provide quicker implementable clinical information models and then to pass their results on to the SDOs for formal standardisation. CIMI specifications will be freely available to all.

CIMI has been holding meetings since July 2011 and it is "dedicated to providing a common format for detailed specifications for the representation of health information content so that semantically interoperable information may be created and shared in health records, messages and documents." Initially it is to use both the openEHR Archetype Definition Language (version 1.5) and a UML profile to represent the same CIMI models. The UML modellers have the stated goal "To provide an ecosystem of tools that underpin and support CIMI activities through the use of an open source approach and adopted standards."

As you would expect proponents of 13606 and DCM are both part of this initiative and TC251 takes an active part in its work. CEN TC251 has observer status at this present time but is committed to following through with the CIMI outcomes in the revision of its associated standards. For more information see http://informatics.mayo.edu/CIMI/

Region Matters

Spot light upon the European Directives

The European Medical Device Directive (MDD) has been considering the regulation of stand-alone health software since March 2010. TC251 formed a European group of experts together with the medical device experts of CENELEC TC62 under the banner, "Software as a medical device" (SAMD). The SAMD group has contributed to the EU guideline document "Qualification and classification of stand-alone software" published as MEDDEV 2.1/6 in January 2012. The MDD is currently being revised, so the SAMD group follows the developments and continues to provide its expert help in this area.

At the same time within ISO, CEN TC251 experts are contributing to, and tracking the work item to do with 'Guidance on standards for Enabling Safety in Health Software'. The work item came directly out of concerns related to the regulation of medical devices and the impact it had upon Canadian industry and services.

European Interoperability Frameworks

The first version of the European Interoperability Framework (EIF) was published in November 2004. It was very top-level and focussed upon Administration, Businesses and the Citizen. A generic interoperability framework (EIF 2) was adopted by the EC as the *Annex II - EIF* of the *Communication "Towards interoperability for European public services"* on the 16th of December 2010. It is part of the wider policy context and landscape for EU eHealth interoperability. The eHealth standardisation mandate M403 considered interoperability with respect to the Health Informatics domain. The original work of TC251 and its European partners arising from M403 led to the 'eHealth-INTEROP report'. For more information on the report's recommendations see http://www.ehealth-interop.nen.nl/

The first workshop to take up some of this work was on 16 April 2012 and attempted to blend the top-down, generic framework with the more bottom-up project based work that had gone before. As well as the INTEROP work, a number of projects were synthesised, serving to highlight both the need for such a framework and the difficulty in delivering any workable solutions. The final workshop is scheduled for September, but consultation and progress are limited at this time. We hope to feature more on the eHealth EIF work in our next newsletter.

Smart Open Services for European Patients: epSOS

epSOS is the main European electronic Health interoperability project co-funded by the European Commission and its partners. It is a large scale pilot that involves 23 different European countries and its goal is to make it feasible to have cross-border eHealth services. epSOS has recently entered its 'operational mode' on the 13th April 2012 and is seeking to make people more aware of its products and benefits via press releases and other activities. For more information see http://www.epsos.eu/

Showcase Standards

Medicinal products: IDMP

In 2007 the 'International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use' (ICH) contacted CEN to support their standardization activities for Identification of medicinal products (IDMP) & Individual case safety report (ICSR) projects. The ICSR work has been published in 2011 as ISO 27953. A group of five standards are now ready for publishing which together provide the basis for the unique identification of medicinal products.

These IDMP standards support the activities of medicines regulatory agencies worldwide by jurisdiction. These include a variety of regulatory activities related to development, registration and life cycle management of medicinal products, as well as pharmacovigilance and risk management. To meet the primary objectives, it is necessary to reliably exchange medicinal product information in a robust and reliable manner. Fully tested messaging specifications were included as an integral part of the IDMP standards to ensure that they were implementable before publication. For example, the IDMP standards support a good number of key exchanges, including the following interactions:

- between one medicine regulatory agency and another, e.g. European Medicines Agency to the US Food and Drug Administration (FDA), or vice versa;

- between medicine regulatory agencies and worldwide-maintained data sources, e.g. the Pharmaceutical and Medical Device Agency (PMDA) and the organization responsible for assigning substance identifiers.

Unique identifiers produced in conformance with IDMP will support applications for which it is necessary to reliably identify and trace the use of medicinal products and the materials within medicinal products. The HL7 led ICSR was developed concurrently with the IDMP standards and both are mutually interdependent. For more information on the uptake of IDMP see the European Medicines Agency PDF at http://tinyurl.com/7sbevpa

Standardisation topics in preparation

TC251 proposes that the specification of the data structures of the 'spirometry test report' is started as a new work item in the JIC. Sweden suggested this topic originally to TC251. It was found that good work had already been done within the Spanish HL7 community and it is believed that this could be the basis for a global standard in this area through the JIC. Those interested in contributing to this work should contact the TC251 secretariat.

Experts are sought to work on a standard for 'Electronic Data Format – Sleep and EEG'. The basis of this work is the well-known EDF+ definition which has been successfully applied both in research collaborations and also in clinical work for several years. The member countries voted positively to start work on this standard earlier in 2012 but there are still a couple of experts needed to start the work formally in TC251. Those interested should contact the working group WGIV convenor Alpo Värri (Alpo.Varri@tut.fi).

Events

Calendar

19-20 July 2012, Rome: CEN TC251 WG1 Workshop on 13606, ContSys and HISA.

26 -29 August 2012*, Pisa, Italy: MIE 2012.*

14-16 September, Baltimore, USA (to be confirmed): CIMI

22-23 September 2012, Vienna, Austria: Joint Initiative Council

23 -25 September 2012, Vienna, Austria: joint CEN & ISO WG meetings

26 September 2012, Vienna, Austria: ISO/TC215 plenary meeting (morning)

26 September 2012, Vienna, Austria: TF SAMD meeting (afternoon)

13-15 May 2013, Dublin, Ireland, Ministerial conference on eHealth

Ballots

At any given time there are a number of ballots occurring in the various SDOs. The ones we would highlight here are two new proposals that are with the NMBs now, for voting on by the 10th August 2012:

- To revise, together, all 5 parts of the 13606 standard under the Vienna Agreement
- The GS1 led, 'Automatic ID and data capture marking and labelling – Subject of care and Individual Provider ID'

Opportunity to work with us

Are you aware of a gap? Do you have something that should be shared with the world? Are you a commercial firm with a solution requiring a world-wide market? Do you wish to propose a new standard or participate as an expert on the standards being developed and delivered? Is your NMB active?

Good Practice & Feedback

Is there something you are proud of and would like to showcase? Do you have experiences (good and bad) of particular CEN TC251 standards? The floor is yours… help us complete the life-cycle by telling us what you use and find helpful.

How can we help more?

This first newsletter should have provided you with a timely update about what is going on with regard to interoperability standards in Europe. Suggestions for improvement and future contributions are particularly welcome. News regarding implementation stories will provide our community with a valuable resource with respect to the usefulness and usability of standards. Contact the editor, Stephen (s.kay@histandards.net) for newsletter related topics and the TC251 Secretariat, (Shirin.golyardi@nen.nl) for all other matters. We look forward to hearing from you, and working with you for the wider HI standards community.