IT-014 Health Informatics Committee

Final Report

ISO/TC 215 Meeting – Chicago, USA

18-21 October 2011

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Date Issued: 16 December 2011
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Collated by: Standards Australia

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- Heather Grain (Delegate)
- David Rowlands (Delegate)
- David Rowed (Delegate)
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1. INTRODUCTION

The International Organization for Standardization (ISO) is the world's largest developer of standards. Although ISO's principal activity is the development of technical standards, ISO standards also have important economic and social repercussions. ISO is a network of the national standards institutes of 162 countries, on the basis of one member per country, with a Central Secretariat in Geneva, Switzerland.

ISO develops health informatics standards through technical committee ISO/TC 215 Health Informatics, which conducts its activities through the following working groups (WGs) and other organisational units:

- TC 215 Executive Council - responsible for executive leadership and strategy
- WG 1 Data Structure
- WG 2 Data Interchange
- WG 3 Semantic Content [Convenor: Heather Grain (Australia)]
- Traditional Medicine Task Force (reporting through WG 3)
- WG 4 Security, Safety and Privacy
- Patient Safety & Quality Task Force (reporting through WG 4)
- WG 6 Pharmacy and Medication Business
- WG 7 Devices
- WG 8 Business Requirements for Electronic Health Records (EHRs) [Secretariat: Australia]
- Operations and Harmonization Committee – coordinates working group activity, secretariat processes and TC 215 work program.

The second ISO/TC 215 meeting for 2011 was held from 18 to 21 October in Chicago, USA and was attended by 9 Australian delegates (with funding assistance provided by the Department of Health and Ageing).

ISO/TC 215’s activities are mirrored in Australia by Standards Australia Technical Committee, IT-014 on Health Informatics.

The benefits that the Australian Healthcare Community derives from Australian representation at international meetings such as this one are significant and ongoing. It is recognised that it is vitally important to ensure that an Australian national position is represented at such meetings. The most effective way of achieving this is to ensure that a delegation is comprised of the appropriate mix of skills and expertise in order that priority areas are comprehensively addressed.

ISO health informatics standards have tended to focus on policy, governance and functional best practice applicable to the eHealth agenda - as opposed to the technical perspective found in HL7 and the content perspective of International Health Terminology Standards Development Organisation (IHTSDO). However, the formal relationships between each of these organisations are being extended through regular meetings of their representatives through the Joint Initiative Council (JIC) resulting in increasing collaborative effort to harmonise standards development along a continuum that includes policy, governance, quality/safety and implementation pathways. As a result, ISO/TC 215 has provided an international forum in which key technical standards such as HL7v2.5, HL7v3 RIM, coordinated data types, HL7v3 CDA R2 and the CDISC BRIDG model are being jointly developed for acceptance as full international standards.
This was the first meeting since the American Health Information Managers Association (AHIMA) took over the secretariat of TC 215 from the Health Information Management Systems Society (HIMSS), both of which are conveniently based in Chicago. The head of international standards activities from the American National Standards Institute (ANSI) attended the meeting on behalf of ANSI as the US national member body of ISO. He provided the TC 215 secretariat with authoritative and helpful guidance on how to approach their role, which will hopefully overcome previous confusion and provide TC 215 with a lasting legacy of practical advice to ensure that the secretariat is efficient and responsive to member needs.

2. OBJECTIVES OF THE MEETING

Australia participates in international standards development activities in accordance with its obligations under World Trade Organisation treaties. The overarching objectives are to benefit the Australian health system and wider community by:

- Improving Australian capacity to implement health informatics standards and eHealth systems by expanding local knowledge and expertise based on international best practice.
- Promoting free trade and its benefits to health ICT (by lowering the cost of integrating and implementing local health information systems, many of which are imported, and by reducing costs to Australian exporters) – both these outcomes require Australian requirements to be embedded into global standards so that they can be adopted in Australia, rather than having different standards across domestic and international markets.
- Improving Australian health information systems by facilitating a standards-based approach to development and implementation, and achieving interoperability between systems.

Specific objectives for Australian engagement in international standardization via ISO/TC 215 (Health Informatics) include:

- Monitoring and influencing ISO/TC 215’s strategic positioning and business model, encouraging it in leading collaboration with other global Standards Development Organisations (SDOs), and assessing and influencing its outputs so as to maximise Australia’s capacity to ensure that our health information interchange and related requirements are supported unambiguously by international standards. A more global approach to standards development was a specific request to ISO from a range of national eHealth programs, including Australia’s.
- Negotiating specific objectives for EHR, Personal Health Record (PHR) and health ICT safety standards.
- Progressing EHR Communication, Data Harmonisation, Subject of Care Identification, Provider Identification, and EHR/PHR Systems requirements standards into and through balloting, and assessing and contributing to other standards required for implementation of EHR and personal health record (PHR) applications, including updates to TS 18308.
- Advocating for consistency between major SDOs currently developing approaches to EHR interoperability, including consistency regarding data types, object constraint models, health information service architectures, and clinical information models and their representation.
- Facilitating consistency and collaboration between global SDOs in development and adoption of health informatics standards – including encouragement of and participation in harmonisation activities through the Joint Initiative Council (JIC) of ISO, CEN, HL7, IHTSDO, CDISC and GS1 and the JIC Harmonisation stream at ISO/TC 215 meetings (ISO TC215 /WG9).
- Leading development of consistent terminology and an approved lexicon of terms and thesaurus for use across all ISO health informatics standards.

- Progressing information security standards, including (where appropriate) encouraging finalization of standards on: Secure archiving of electronic health records; Security management in health using ISO/IEC 27002; Privilege management and access control (PMAC); Audit trails for electronic health records; Functional and structural roles; Information security management for remote maintenance of medical devices (guideline); Dynamic VPN access to health networks, and EN13606 Part 4 within ISO.

- Supporting the proposed liaison between ISO/TC 215 and ISO/IEC Joint Technical Committee 1 (JTC 1) with a view to encouraging collaboration on IT standards affecting health care delivery and avoiding duplication of work.

Relevance to NEHTA programs - NEHTA has endorsed a range of Australian Standards derived from international standards work some of which were included in a National eHealth Standards Catalogue. A more recent review has identified many of potential relevance to the development of the Personally Controlled Electronic Health Record (PCEHR). As the implementation of PCEHR and other eHealth initiatives is based on a growing body of these standards, it is important that Australia continues to be involved in the international forums that develop, manage and maintain these, and other potentially relevant, health informatics standards.

ISO/TC 215 holds two full international meetings per year. The first (in May) is known as the “Plenary Meeting” because it includes plenary sessions in which formal resolutions are taken in addition to meetings of TC 215’s eight domain-specific working groups.

The second meeting, (in September/October) is the “Joint Working Group Meeting” because it mainly comprises meetings of the working groups but, in recent years, has also included a smaller “mini-plenary” to progress urgent matters.

The event is a true working meeting, not a conference, with many individual groups meeting to develop, discuss and improve ISO standards, processes and implementation guides and to determine the most effective way to meet the needs of the stakeholders – both those present at the meeting and those in the wider community of interest.

The meeting proper was preceded by a one-day working session of the Joint Initiative Council (JIC) in open forum. The Australian delegation also met on the evening before the official meeting commenced.

This particular Australian delegation had a good mix of skills and, given that two working groups did not meet on this occasion, was able to cover most aspects of the meeting.
3. **AGENDA**

The agenda for the four days of the TC 215 meeting (including JIC pre-meeting) was as follows:

<table>
<thead>
<tr>
<th>TUESDAY 18 OCTOBER 2011</th>
<th>0800 - 1700: Registration 14th Floor Foyer</th>
<th>0830 - 0900: Tea / Coffee Break</th>
<th>0900 - 1100: Joint Initiative Council (JIC) Meeting</th>
<th>1200 - 1300: JIC Group lunch at Holiday Inn restaurant - purchase own lunch under special provided menu</th>
<th>1330 - 1600: Tea / Coffee Break</th>
<th>1600 - 1800: Joint Initiative Council (JIC) OPEN Forum</th>
<th>1800 - Registration 14th Floor Foyer</th>
<th>1830 - 2000: Executive Council Meeting - Working Dinner - Invitation Only (HOD’s - Convener’s - Vice Convener’s) - Room: Wolfe Point</th>
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<td><strong>Friday 21 OCTOBER 2011</strong></td>
<td><strong>AGENDA</strong></td>
<td><strong>TC/215 - WG 1 &amp; 8</strong></td>
<td><strong>TC/215 - WG 9</strong></td>
<td><strong>TC/215-WG 4</strong></td>
<td><strong>WG 6</strong> Task Force</td>
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# THURSDAY 20 OCTOBER 2011

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<th>Time</th>
<th>Session</th>
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<th>Notes</th>
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| 9:00 - 10:30 | Q1 | SAUGANASH EAST | Chair: Stephen Kay  
- ISO 13972 Quality requirements and methodology - detailed clinical models (1 & 2)  
- Organization of the Pl 2 document / review part 1 and what needs to go into part 2 |
| 10:00 - 10:30 | TC/215 - WG 1 & 8 | STEAMBOAT | Joint Session  
- Quality Measures for TeleHealth TS 13131  
- Coordination: ITU-T SG 17 Request for comments on draft Recommendation-integrated framework for telebiometric data protection in e-Health and worldwide telemedicine |
| 10:30-10:45 | Q1 | WESTERN STAGE | Tea - Coffee Break |
| 10:45 - 12:15 | Q2 | SAUGANASH EAST | Joint session with WGs 1, 3, 8: ISO/CD 13940 – System of concepts to support continuity of care – Status report; walk-through of website - WebEx |
| 12:15 - 13:15 | Q3 | SAUGANASH WEST | 56 down lunch [Meal Ticket] |
| 13:00 - 15:00 | Q4 | SAUGANASH EAST | Closing Plenary |

# FRIDAY 21 OCTOBER 2011

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<th>Time</th>
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<td>11:00 - 12:15</td>
<td>TC/215 - WG 1 &amp; 8</td>
<td>SAUGANASH EAST</td>
<td>Closing Plenary</td>
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| 12:15 - 13:00 | Q5 | AMERICAN HOUSE | Lunch Buffet  
- WG3 and WG8 final discussions |
| 13:00 - 15:00 | Q6 | SAUGANASH EAST | Closing Plenary  
- WG 4 Final discussions |

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**Note:** All WGs must provide Resolution drafts to the Secretariat staff by 1330 on Thursday 20 October to allow staff enough time to make copies and provide this information to the Delegations at the start of their 1715 meetings. Conveners will provide additional details. Note: Secretariat staff room is "Mansion House" and is in the same area as all WG mtgs.

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**Social Activity:**  
Cocktail Reception

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**FRIDAY 21 OCTOBER 2011**

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<th>Time</th>
<th>Session</th>
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<td>8:00 - 10:00</td>
<td>TC/215 - WG 1 &amp; 8</td>
<td>SAUGANASH EAST</td>
<td>14th Floor Foyer</td>
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<tr>
<td>10:00 - 12:15</td>
<td>TC/215 - WG 3</td>
<td>STEAMBOAT</td>
<td>14th Floor Foyer</td>
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| 12:15 - 13:00 | Q7 | AMERICAN HOUSE | 15:00 - 16:30: WG2 Closing Plenary  
- WG2 Closing Plenary |
| 13:00 - 15:00 | Q8 | SAUGANASH EAST | 15:00 - 16:30: WG2 Closing Plenary  
- WG2 Closing Plenary |

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**Friday Night Activities:**  
Cocktail Reception

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**Registration:**  
Wednesday 19 October 2011

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**Secretariat:**  
- ISO/IEC 17117-1 – Terminological resources:  
  Part 1 – Characteristics:  
  Part 2 – Channels:  
  Part 3 – New Work item proposals - TMA-TF  
- Review resolutions to mini plenary  
- Other business & future meeting dates  
- 16555 Framework for National Health Information Systems - Results of NWIP ballot and disposition of comments Motion for DTS ballot  
- 27799 ISM in Health using ISO/IEC 27002  
- Vote on final report on ISM strategy  
- 22600 PMAC Update  
- 16114 Security aspects of EHR migration  
- 23001 PMAC Update  
- 10159 ISO/IEC 27002 - SR ballot review & revision strategy  
- 16864 Data protection in trans-boundary flows of personal health information

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**Additional Information:**  
- Quality Measures for TeleHealth TS 13131  
- Coordination: ITU-T SG 17 Request for comments on draft Recommendation-integrated framework for telebiometric data protection in e-Health and worldwide telemedicine

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**Contact Information:**  
- Standards Australia Limited
- Phone: +61 1300 303 197
- Email: info@sa.org.au
- Website: https://www.sa.org.au
4. RECOMMENDATIONS ARISING FROM THE MEETING

The principal issues / actions and recommendations identified by the Australian delegation at the October 2011 ISO/TC 215 meeting are summarised in this section. Alignment to the IT-014 Committee Structure is also listed.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Issue/Action and Recommendations for Australia</th>
<th>Suggested responsibility &amp; alignment to IT-014</th>
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<tbody>
<tr>
<td>JIC Open Forum</td>
<td>JIC has begun having open forums and as work crosses other SDOs in which Australian delegates are actively working, these members should be encouraged to attend the JIC meetings. <strong>Action:</strong> Australian delegates, be encouraged to attend the now-open JIC meetings.</td>
<td>Standards Australia</td>
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<td>JIC All WGs Cross-SDO meeting planning</td>
<td>With JIC developing a meeting plan which goes further into the future and some meetings being co-located, one after the other, we should consider how to opportunistically ensure coverage and mentoring within our ISO, HL7 and potentially IHTSDO delegations to improve coverage while managing costs. <strong>Action:</strong> Consider how to leverage potential upcoming consecutive and/or co-located meetings to extend delegation construction/skill representation while maintaining a reasonable cost of engagement.</td>
<td>DoHA IT-014</td>
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<td>All WG’s Getting access to working documents, presentations, past minutes and emails</td>
<td>Some members of the Australian delegation expressed concern that they had not been able to get access to archived documents, past emails, presentations, and working drafts of standards. This made it difficult for them to develop an in-depth understanding of projects being discussed and balloted, where they had not previously been closely involved in a particular project. Particularly if there is to be variation in the Australian delegation from meeting-to-meeting or where members are asked to cover an area with which they are not familiar, then this needs to be addressed. Some of these problems may have been due to changes in moving to the secretariat to AHIMA and changes in arrangements for hosting and managing both the TC 215 and several of its WG websites. Improvements also need to be made to the processes for preparing Australian delegates to attend TC 215 meetings. <strong>Action:</strong> Secretariats be requested to make WG committee working areas and site maps for all of the above types of material clearly known to delegates prior to meetings. Delegates be instructed to check access for the WGs they propose to attend, that they can find the different types of documents they will need, and to check that their names are on the WG mailing lists which are supposed to be available in the WG area</td>
<td>ISO Secretariat SA (at delegate pre-WG meetings)</td>
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<td>WG1, 3 &amp; 8 System of concepts to support continuity of care (Contsys) JIC</td>
<td>Contsys was originally a European (CEN) standard and is potentially one of the more significant pieces of work undertaken by the international standards community and, as an ISO standard, promises to be useful to support interoperability, referral and PCEHR activities Contsys is an integrative, high level model which covers areas typically developed in isolation - content, terminologies and concepts, interactions, messages and health records – and relates them to underlying care processes. The system of concepts supports continuity of care, bringing together high level ideas of how business and clinical content fits together.</td>
<td>IT-014 NEHTA HL7 Delegates Jurisdictions</td>
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<td>HL7 has developed many use cases and models of clinical concepts which are represented at an abstract level by DAMs. HL7's approaches tends to have been independent of other modelling approaches including DCMs. Australian experts consider that there would be considerable benefit in using Consys to drive greater alignment between HL7 DAMs and DCMs as implemented in Australia. Now Consys is a JIC project Australia can more strongly encourage participation in its development and its adoption by other JIC members, including HL7.  &lt;br&gt;<strong>Action:</strong> IT-014 to seek active engagement from NEHTA, the jurisdictions and its working groups within IT-014 to provide active input to the development of Consys.  &lt;br&gt;<strong>Action:</strong> IT-014-06-06 and NEHTA to review Australian implementation guides for Referral and Discharge, related Structured Documents and CDA specifications against Consys for consistency of concepts and models.  &lt;br&gt;<strong>Action:</strong> HL7 WGM delegates to continue encouraging HL7 (and its Patient Care WG) to participate in development of Consys through the HL7 JIC representation.</td>
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<td><strong>IT-014</strong> to monitor and contribute to development of TR 17991 Guidance on Standards for Enabling Safety in Health Software by seeking to involve experts across all healthcare sectors and in all relevant agencies.</td>
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|       | • Extracting Quality metrics from part 2 and re writing it for a CD ballot, including reference to a subsequent part dealing with this;  
|       | • Agreeing to working up a proposal for a new, separate area, at this stage as a part 3 for the material currently addressed in part 2.  
|       | **Action:** IT-014-09 to arrange discussion and lead preparation of ballot response and comment on the ballot of ISO/CD 13972 Part 1 (expected November) and ISO/CD 13972 Part 2 (expected December) – with a view to ensuring that Australia’s concerns are addressed. | |
|       | **WG1 ISO 13972 Quality requirements and methodology for DCMs Part 3** | IT-014-09 NEHTA |
|       | Work has not commenced on Part 3 and in order to participate, Australia would to see value in Part 3 commensurate with the likely resource allocation required to contribute meaningfully to the work.  
|       | **Action:** IT-014-09 to consult with NEHTA and other clinical modelling stakeholders and identifies the content, development process and timeframes likely to be needed in development of Part 3 of ISO 13972 and evaluates whether the level of resourcing required can be found to work allocate. on Part 3 | |
|       | **WG1 ISO 13972 bindings to concept codes** | IT-014-09 |
|       | Within the TC 215/WG 1 expert group working on ISO 13972 there is disagreement over obligatory bindings to concept codes. Based on their experiences, the Australian team feel this will lead to non-workable applications.  
|       | **Action:** IT-014-09 to investigate implications of obligatory bindings and submit its findings to the ISO 13972 project team. | |
|       | **WG1 Diagram in ISO 13972 Part 2** | IT-014 Standards Australia |
|       | A diagram reproduced in Part 2 of ISO 13972 Quality requirements and methodology for [DCMs] was originally developed by Heather Grain and Evelyn Hovenga. They have indicted that they are prepared to share this intellectual property with the standards community at no cost but the source and copyright need to be acknowledged.  
|       | **Action:** IT-014 to obtain detailed background from the original authors of the relevant diagram in ISO 13972-2 and seek advice from Standards Australia on how the licensing of their intellectual property for use in this standard is best addressed. | |
|       | **JIC CDISC Use of standardised data in clinical research** | DOHA NHMRC IT-014 |
|       | Much clinical research is done on an international scale by multinational companies and they often enforce their own methods and models for data collection, meaning compliance with multiple standards for healthcare organisations involved in such research.  
|       | During the JIC Open Forum, Bron Kisler of CDISC presented on their progress toward realising a vision of informing patient care and safety through higher quality medical research including greater use of standards for aggregate data analysis.  
|       | This includes seeking to achieve significant progress in the use of core condition-specific CDISC standards to facilitate scientifically sound data aggregation and support secondary uses of research data for scientific investigation and comparative effectiveness studies.  
|       | The CDISC vision of widely adopted international standards in this area could improve the quality of research data and the ability to re-use and compare research conducted over time as well as to improve our national data collections. It could also lead to significant cost savings in research.  
<p>|       | Use (and re-use) of trial data in clinical research is a long standing issue in Australia where there is no requirement for nationally funded research to use and inform national data collections and metadata. | |</p>
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| Action: Engage with NHMRC to improve the relationship of nationally funded research to national data collections and metadata specifications.  
Action: IT-014 to consider how to leverage the CDISC work in Australia |

WG2  
ISO TR 13128  
Clinical document registry federation  
ISO TR 13128 defines an extension to the IHE Document Registry in order to allow a federated registry/access model.  
TC 215 agreed at its last meeting in May 2011 that the draft should proceed to publication; however, publication was delayed. Matters are now back on track and no further action was required from TC 215 at this meeting.  
Action: None required from IT-014. Standards Australia to note. |

WG2  
ISO/TS 13131  
Quality Criteria for Services and Systems in Telehealth  
This work seeks to define criteria for a process or set of processes aiming at improving or enabling health and health care using information technology and telecommunications to reduce the effect of distance in space and/or time between the actors.  
By the last TC 215 meeting (Finland, May 2011), a third draft had been produced, and it was resolved that the DTS ballot should be placed on the ISO/TC web site by July 2011. Despite the requisite documentation having gone to the ISO Central Secretariat the document has never been balloted. This will be followed up by the TC 215 Secretariat.  
Action: IT-014-012 to advise on the NP ballot, when posted. If there are no serious comments then hopefully there can be resolution of issues prior to the next ISO meeting in May 2012. |

WG4  
Integrated framework for tele-biometric data protection in eHealth and worldwide telemedicine  
Developed by ITU-T as a new recommendation (TD 1818 from Study Group 17), focus is on mandating use of biometric identification technology to support interoperability in cross borders, cross community and peer to peer sharing of healthcare data in a one to many environment.  
This item had been discussed at a joint meeting of WG 4, WG 2 and WG 7 at the May meeting of TC 215 and many concerns had been raised. Further discussion on this topic in WG 2 indicated that the concerns continue and that this work (if it is to be done at all) would be more appropriate to be led by ISO/TC215 (rather than ITU-T/SG 17) and needed to include WG 4 (Security, Privacy and Safety).  
Action: IT-014-12 and delegation to next TC 215 meeting to monitor for progression and suitability of this work item |

WG2  
NP: deployment of global standards in collaboration with IHE.  
This Work Item progresses some of the Integrating the Healthcare Enterprise (IHE) procedures into ISO standard documents to strengthen the approaches for better and more interoperable implementations of the DICOM and HL7 standards and provide a clearer relationship between IHE initiatives and those of the standards community.  
Two parts of a Technical Report (TR 28380) are being produced, dealing with:  
- The IHE global standards adoption process (Part 1); and  
- IHE Integration and Content Profiles (Part 2) |

Standards Australia  
IT-014-12  
IT-014-06  
IHE Australia  
HL7 Australia
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<td>Unfortunately, despite a positive vote in August 2007, the approved drafts have yet to be updated into final ISO form and published. They have already been published as IHE documents. The positive development at this meeting is that IHE’s relationship with ISO/TC 215 has progressed to “Liaison A” status, which means that the documents should be able to be published largely in their source formats, with four introductory ISO clauses. This is a relatively easy task, whereas the previous requirement was formidable and a substantial barrier to progress. WG2 also determined that a third and final part of this technical report is required, describing how to use the IHE specifications. Collectively, the 3 part series will provide a Technical Report describing the realm of IHE and how to leverage it in standardisation. A ballot of “Health informatics - Messages and Communication - IHE Global Standards Adoption Process Part 3 - Deployment” will be conducted for approval as a new work item targeting a Technical Report. <strong>Action:</strong> IT-014-06 to liaise with IHE Australia and other relevant stakeholders to keep publication pressure on the first 2 parts, and consider the third.</td>
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<td>ISO/HL7 21731:2006 Health informatics - HL7 version 3 - Reference information model - Release 1 was published in 2006. HL7 has an ongoing maintenance process that produces a new release of the HL7 Reference Information Model (RIM) annually. Release 4 is scheduled for publication by HL7 International in Nov/Dec 2011. A critical issue is that HL7 International has in place an annual process to update the RIM, whereas ISO’s publication processes are slower. After consideration of options, it was determined that the ISO version will be updated on a two yearly basis, since year to year changes are now generally relatively minor. A fast-track process under the ISO-HL7 Agreement will be used, whereby if approved as a new work item, the new release can proceed directly to DIS ballot. <strong>Action:</strong> Support revision of the HL7 V3 RIM as an ISO standard together with a process for practical, periodic updates to track the releases at HL7.</td>
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<td>This Work Item (IS 13449) deals with pedigree representation (including visualisation) providing standard clinical representation not seen as suitable for other Health IT purposes. IS 13449 passed DIS ballot in April 2011, and all comments were resolved at the last TC 215 meeting (Finland, May 2011), at which the TC agreed that the revised document should proceed to publication. However, it appears that the requisite documentation has not yet been forwarded to the ISO Central Secretariat. The WG2 Convenor / TC 215 Secretariat will follow up and facilitate this item proceeding to publication as previously intended. <strong>Action:</strong> None required from IT-014. Standards Australia to note.</td>
<td>IT-014, IT-014-06-06 NEHTA</td>
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<td>Standards Australia</td>
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| **WG2 TR 17522 Provision for Health Applications on Mobile and Smart Devices.** | This work item addresses issues around the provision of Health Applications on Mobile/Smart Devices. Beyond simple video conferencing, this requires diverse services/capabilities such as displaying measurements and other relevant clinical documents and information consistently across a range of devices. It recently passed NP ballot and, at this meeting, comments provided during the NP ballot were disposed. It was noted that there is a relevant IHE work item in the pipeline (XDS for mobiles), and accordingly IHE will provide a liaison to this project. Australian developers and users have been looking at the need to develop standards for modularisation in the application space, and taking this through Patient Care, SOA and CDS in HL7. There is no one place in Standards Australia to address these functionally decomposed, inter-component needs.  

**Action:** Set up a task force within the Australian Standards, industry and user communities to organise this work, articulate strategy and support this project at ISO through wide distribution and engagement in these communities. Advance this also through HL7 International at PC, SOA, CDS and RIMBAA. | Standards Australia, MSIA, HL7 Australia, HL7 WG Delegations, IHE Australia, DoHA and RACGP |
| **WG2 ISO 14199 BRIDG Domain Analysis Model for protocol-driven biomedical** | The "Biomedical Research Integrated Domain Group" (BRIDG) is a collaborative effort to produce a shared view of the dynamic and static semantics of protocol-driven research and its associated regulatory artefacts. It is intended to streamline information flows from protocol development through analysis and reporting within organisations and will facilitate data sharing across partnering organisations, including healthcare and clinical research entities. BRIDG is an important step toward achieving integration between the worlds of healthcare delivery and medical research. A JIC project sponsored by ISO, HL7, and CDISC is taking the BRIDG model, which was originally developed by CDISC and HL7, through to an international standard. It is potentially important for internationally communicable cooperative research which involves Australia. BRIDG first became an official CDISC standard in May 2009. In August 2010, BRIDG 3.0.2 was released and this version is being used as the basis for the proposed publication of the joint version by CDISC, ISO and HL7. The draft publication went to ISO Central Secretariat for circulation with a DIS ballot. However, there are some formatting issues, and CDISC is working with the Central Secretariat to resolve them. There are also issues synchronising maintenance of the ISO publication with updates to the underlying BRIDG model. A fast track process has been agreed for updating the model which will involve a hybrid arrangement with CDISC providing material for 2 yearly DIS ballots.  

**Action:** Australian delegations to TC 215 to support the fast-track approach at ISO, identify and engage the Australian research communities to ensure this meets their requirements. Ensure the process at HL7, and from there at CDISC, is conducive to ISO process needs. | Standards Australia, NHMRC, HL7 International Delegation |
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<td><strong>WG2</strong>&lt;br&gt;<strong>Clinical Trial Registration and Reporting (CTR &amp; R)</strong></td>
<td>The primary purpose of CTR&amp;R standard is to provide seamless data exchange between global pharmaceutical sponsors and clinical trial registration authorities such as US (ClinicalTrials.gov), European Medicines Agency (EMA) (EudraCT) and WHO (Clinical Trial Registry). It is proposed as a 2-part standard with Part 1 intended to meet global requirements for clinical trials registration with Part 2 for reporting of trial status and summary results. It was resolved at the last TC 215 meeting in May 2011 that the ISO/TC 215 Secretariat should circulate an NP ballot for approval as a new work item targeting an International Standard using the fast-track process. Unfortunately, this did not happen but will now be pursued. <strong>Action:</strong> On receipt of the ballot documentation, IT-014 to seek input from the local clinical trials community on Australian perspectives and potential participation in the work.</td>
<td>Standards Australia NEHTA TGA</td>
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<td><strong>WG2</strong>&lt;br&gt;<strong>Web Access to DICOM persistent Objects by means of Web Services ISO 12974 Supplement 148 - WADO</strong></td>
<td>Web access to DICOM imaging objects (&quot;WADO&quot;). This work proposes that the original ISO 17432:2002 Web access to DICOM persistent objects (WADO) standard should be expanded with new web services enhancements. This now forms part of the DICOM standard, in the form of a supplement (Supplement 148: Web Access to DICOM Persistent Objects by Means of Web Services Extension of the Retrieve Service (WADO Web Service)). A joint TC 215/DICOM project team is to make minor changes in order to finalise the WADO-WS document using the “cover sheet” approach for publishing existing standards from ISO Liaison A organisations. A DIS ballot is expected to issue around March 2012 (following a joint meeting of WG2 at the January 2012 HL7 WGM in San Antonio). Web access to imaging takes place in the Australian health community with clinicians accessing material in private imaging centres through proprietary products which require deployment on client systems. Future directions in Australia, backed by work at NEHTA indicate a move towards services-based solutions for clinical data sharing. <strong>Action:</strong> IT-014-06 to track progress at the review next WG2 meeting and prepare ballot response and comments with input from NEHTA and other experts.</td>
<td>IT-014-06 NEHTA</td>
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<td><strong>ISO/TR 12310 Conformance of terminological systems - Australian comments</strong></td>
<td>Though some Australian comments have been received on ISO/TR 12310 Principles and guidelines for the measurement of conformance in the implementation of terminological systems this work should be reviewed by the NEHTA CCA group to ensure our requirements are appropriately reflected. <strong>Action:</strong> Obtain and submit NEHTA comments. All comments are required to reach the secretary by the end of November.</td>
<td>NEHTA</td>
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<td><strong>WG3</strong>&lt;br&gt;<strong>DTR 13054, Standards Knowledge Management</strong></td>
<td>DTR 13054 is about to be sent for publication. IT-014 have agreed to contribute to the SKMT activity, as have other countries; however resources have yet to be made available for this task, though it is understood that funds have been established through NHISSC. NEHTA should be included in this process to allow them to determine whether to load their data into the tool to support a coordinated approach.</td>
<td>IT-014 NEHTA IT-014-02</td>
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<td><strong>WG3 Decision Support and Alerts</strong>&lt;br&gt;TS 14668 Parts 1 to 3</td>
<td>Work on developing ISO/TS 14668 Guidelines for the principles and desirable features of clinical decision support systems is based on earlier Australian IT-014 work and is in three parts:&lt;br&gt;1. System foundations,&lt;br&gt;2. Technical foundations, and&lt;br&gt;3. Alert system requirements&lt;br&gt;This work potentially has a direct relationship to PCEHR and other NEHTA activities. As Australia is leading work on all three components, which are also potentially relevant to NEHTA activities, active NEHTA engagement should be sought both to inform NEHTA activities of this work and to gain input from them.&lt;br&gt;A need for greater clarification over definitions, relationships to work in HL7 and potential further activities in standards for clinical decision support was also raised by some of the Australian delegates&lt;br&gt;<strong>Action:</strong> Seek active engagement of NEHTA in this work and ensure clinical, administrative, and technical input to the work.&lt;br&gt;<strong>Action:</strong> Australian delegates to HL7 WGM to work with HL7 CDS WG to arrive at common definitions for CDS concepts and to include them in the SKMT.&lt;br&gt;<strong>Action:</strong> IT-014 to implement recommendations from recent meetings and form a CDS task force involving key stakeholders with a view to building upon TR 14668 and developing a framework for CDS standards that address Australian requirements. Work needs to be cognizant of existing and HL7 products and gaps, and take the work through HL7 and ISO ultimately targeting JIC level.</td>
<td>IT-014&lt;br&gt;NEHTA&lt;br&gt;HL7 Delegates attending CDS</td>
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<td><strong>WG3 Expressing terminology constraints on coded data elements (with WG2)</strong></td>
<td>The proposed new standard, ISO 17583 Health informatics – Terminology constraints for coded data elements expressed in ISO harmonized data types used in healthcare information interchange, is based on previous HL7 work on &quot;terminology binding&quot; coming into ISO. It describes how to apply terminology to particular data elements, for example in information models, data dictionaries, etc. and will enable people to formally demonstrate that the way they have constrained is valid in terms of the source standards.&lt;br&gt;The draft specifications have had extensive review in HL7, and draw from substantial practice in Canada Health Infoway.&lt;br&gt;This work item is highly relevant to Australian requirements and the NEHTA community as well as IT-014-06 and IT-014-02 and all should be actively reviewing and participating in discussions.</td>
<td>IT-014-02&lt;br&gt;IT-014-06&lt;br&gt;IT-014-09&lt;br&gt;Collaborating with:&lt;br&gt;NEHTA&lt;br&gt;HL7 Australia&lt;br&gt;IHE Australia</td>
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| The item recently passed NP ballot as a new work item with experts being nominated, including from Australia. It was noted that discussion is required on comments from UK and Australia, and this will be sought by the project leaders. Australia proposed that IHTSDO be included as liaison, and this was agreed.  
**Action:** IT-014-02, IT-014-06 and IT-014-09 to track this work item and collaborate with NEHTA, HL7 Australia and other key stakeholders to inform Australia’s position. |                                                                                                                                                                                                                                               |                                               |
| **WG3 OID Registries**                                     | Consider whether an expert is needed to represent Australia’s position on this work and if so provide a name to the Secretary of WG3 to ensure that they get the opportunity to comment at the earliest point.  
**Action:** IT-014 to determine the interest of Australia in this work activity and if appropriate determine the expert to contribute, IT-014-02 to provide oversight. | IT-014                                       |
| **WG 3 & TMTF Categorial structures for herbal medicaments in traditional medicine** | Categorical structures for representation of herbal medicaments in terminological systems seeks to address the situation where regional linguistic differences and history have led to the use of single specific names representing different materials or natural medicaments, i.e. different names often designate same natural medicament. One of the key aims is to prevent risk to patient safety.  
TC 215 resolved to issue an NP ballot for a new work item in this area.  
**Action:** IT-014 to support proposed work on categorial structures to standardise terminology for herbs used in traditional medicine and provide comment and named expert(s) in response to | IT-014                                         |
| **WG3 & TMTF TCM Literature Metadata**                    | Proposed ISO/TS Traditional Chinese Medicine Literature Metadata. The academic TCM community in Australia is strong and would have a direct interest in this work.  
**Action:** Seek active engagement of the TCM academic community in Australia to provide input to these work items and to advise on our support, or otherwise of these work items. | IT-014 Standards Australia                   |
| **WG3 & TMTF Semantic network framework & coding of TCM language systems** | Proposed ISO/TS Semantic network framework and coding of literature of Chinese medicine language system. This work underpins the development of a ‘version of UMLS’ that represents TCM and which the WG members believed would underpin the capacity to mine TCM literature.  
The academic TCM community in Australia is strong and would have a direct interest in this work.  
**Action:** IT-014 to seek expert input on receipt of NP ballot for Semantic network framework and coding of Traditional Chinese Medicine language system, which is relevant to Australian interests in complementary medicine. | IT-014 Standards Australia                   |
| **WG4 Security, privacy & Safety ISO FDIS 21091 Directory services** | ISO FDIS 21091 on directory services for health care providers, subjects of care and other entities may directly affect present and planned health service directory implementations in Australia. There may be some privacy aspects that need to be assessed in the standard.  
**Action:** IT-014-06 and IT-014-04 to review FDIS for any issues that would adversely affect existing or planned directory services implementations in Australia. | IT-014-06 and IT-014-04                     |
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| WG4  | Australia will need to respond to the DIS ballot on ISO 17090. AS 17090 parts 1-3 were published in 2003 by Standards Australia and will need to be revised to align with this revision.  
Action: NEHTA and IT-014-04 to continue involvement and monitor changes and impact on AS/ISO 17090 1-3 and harmonisation with current NASH work. | IT-014-04  
NEHTA |
| WG4  | Progress on this item needs to be reviewed and closely monitored by IT-014 to see that this is in alignment with current work occurring in Australia by NEHTA in relation to digitally signing CDA documents.  
Action: NEHTA, IT-014-06 and IT-014-04 to continue involvement and monitoring of impact of ISO 17090-4 Digital Signatures for healthcare documents on current work. | NEHTA  
IT-014-06  
IT-014-04 |
| WG4  | There are a number of concerns about the scope of the proposed NP on Requirements for Consent for the Collection, Use and Disclosure of Personal Health Information and the implied constraints that such a standard may place on other legal and local aspects of consent, use and disclosure of health information. The obsolete but often used AS 4400:1995 Personal privacy protection in health care information systems faced many similar challenges and may provide some guidance for this work  
Action: IT-014 to continue involvement and monitoring of this NP. | IT-014 |
| WG4  | Joint ISO/European work on ISO/EN 16864 Data protection in trans-border flows of personal health information is of growing relevance as jurisdictions look to provide trans-border access to EHR information. Nevertheless, this work item will not progress until relevant experts are found.  
Action: IT-014 to seek an Australian expert to nominate for work on development of ISO 16864. | IT-014 |
| WG4  | Still to be determined the course of action taken as a result of the review, whichever way it progresses a team of experts is required and Australia has stated we will provide to progress the re-issue of this standard.  
Action: IT-014-04 to seek an Australian expert to nominate for work on development of ISO 27799. | IT-014-04 |
| WG4  | It is unclear exactly where the work on PMAC and its revision to a full international standard sits in the Australian context of IT security standards and work such as NASH.  
Action: Recommend IT-014-04 review the Draft document to seek an Australian position on the publication and the relevance of adopting this locally. | IT-014-04  
NEHTA |
| WG4  | It is unclear exactly where DTS 14441 Security & privacy requirements of EHR systems for use in conformity assessment (Parts 1 & 2) sits in the Australian context of IT security standards and work such as NASH and our CCA activities.  
Action: IT-014-04 to review the Draft document to seek an Australian position on the publication and the relevance of adopting this locally. | IT-014-04  
NEHTA |
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| WG8 ISO DIS 16527 PHR system functional model | Australia should continue to keep a watching brief on this work, in reference to its potential impact on the shared EHR applications, which may proliferate as conformant repositories linked to the PCEHR. The principal work on developing a standard from the current HL7 DSTU is progressing through the HL7 EHR WG,  
*Action: IT-014-09 to maintain a watching brief and arrange expert comment when balloted in ISO (mid to late 2012).* | IT-014-09 |
| WG8 ISO DIS 10781 EHR System Functional Model Release 2 | Australia should continue to keep a watching brief on this work. The principal work is progressing through the HL7 EHR WG,  
*Action: IT-014-09 to maintain a watching brief and arrange expert comment when balloted in ISO (early 2012).* | IT-014-09 |
| WG8 ISO 13606 Electronic health record communication | At the May 2011 meeting, it was agreed that all 5 parts of ISO 13606 should be reviewed together as a bundle and a New Proposal (NP) submitted for systematic review at that time in May 2012. It is an opportunity for Australia to put forward constructive changes to re-align these standards with the openEHR specifications from which they originated some 7 years ago and to include some of the learnings from the subsequent implementation-driven development of openEHR.  
*Action: IT-014-09 to monitor and prepare to become involved in systematic review of all ISO 13606 documents in May 2012 and consider adoption into Australia.* | IT-014-09 |
| WG 8 Capacity-based eHealth architecture roadmap Part 1: Overview of national eHealth initiatives | The report builds on lessons from many countries and was largely inspired by experience with the Health Metrics Network (HMN) activities sponsored by the World Health Organization (WHO). This work has been motivated in part by a recognition that countries vary in terms of readiness and resources for health system strengthening, with the expectation that it will help to provide the tools needed for policy-making, strategic planning and eHealth architecture development for robust and appropriate country HIS. The document has been completed, accepted and is in the process of being published  
*Action: IT-014-09 to advise parties that have already expressed interest in the document of its publication, when that occurs.* | IT-014-09 |
| WG 8 Capacity-based eHealth architecture roadmap – Part 2: architectural components & maturity model | Many contributors/editors have been involved developing this document (TR 14639 Part 2) and more detailed contributions now exist for about half the sections.  
Completion of draft is now expected in the first half of 2012 (with Richard Dixon Hughes of Australia being one of the authors).  
*Action: IT-014-09 to monitor progress, review the document and consider contributing expert information to other sections of the draft document.* | IT-014-09 |
| WG8 NP EHR Clinical Research Profile | Australia recently voted against this work because of incompatibility between the existing HL7 Clinical Research Profile based on the existing international ISO 10871 EHR-S Functional Model standard and this proposal to base the new standards on the non-standard EuroRec specifications. A close watching brief is being maintained on this work, which was also referred to JIC  
*Action: IT-014-09 to maintain a watching brief and promote a unified approach in going forward as an ISO standard.* | IT-014-09 |
### TC 215 Exec Council Reorganization Task Force

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<td>The Executive Council and TC 215 plenary requested that Richard Dixon Hughes (Australian HoD) lead a piece of work to make recommendations for improving TC 215 project assessment processes. <strong>Action:</strong> Richard Dixon Hughes to investigate and report at the May 2012 plenary meeting on the possible methods of aligning the prioritisation, selection and approval of work items with TC 215 strategic objectives, working in collaboration with the TC 215 Task Force on Re-organisation and Business Planning.</td>
<td>Richard Dixon Hughes</td>
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### Executive Council JIC - upcoming TC 215 meetings

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<td>TC 215 is looking to establish a 5-year meeting schedule and coordinate through JIC with other Health Informatics SDOs to minimise clashes. Having been the host in 2002 and again in 2007, it is again getting around to being Australia's turn and we certainly need to plan to be host some time in the next 5 years, which will incur some cost. <strong>Action:</strong> IT-014 and Standards Australia to agree on a date and terms on which Australia can commit to host a TC 215 meeting within the next 5 years – before the May 2012 plenary – and consider how this might be funded.</td>
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### Public Health Task Force (PHTF)

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<td>At the May 2011 meeting, a Public Health Task Force (PHTF) was formed with an extremely wide scope. The PHTF is being used as a vehicle to promote and seek financial support for a range of standards activities and policy changes – particularly to benefit low and middle income countries (LMICs). How the longer-term activities of the PHTF relate to TC 215 as a standards committee is somewhat unclear but there have been some moves to use it as a vehicle to progress work on several current WG 8 work items. <strong>Action:</strong> IT-014 to monitor PHTF developments but not seek to become actively involved other than participating to the extent that the PHTF becomes the vehicle to complete existing standards work items and considering any request to share relevant information or to provide assistance or mentoring for LMIC standards work in our region.</td>
<td>IT-014 IT-014-09</td>
</tr>
</tbody>
</table>

### Public health standards needs Consideration of engagement with PHDSC and HL7

<table>
<thead>
<tr>
<th>Topic</th>
<th>Issue/Action and Recommendations for Australia</th>
<th>Suggested responsibility &amp; alignment to IT-014</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The US-based Public Health Data Standards Consortium (PHDSC) – <a href="http://www.phdsc.org">www.phdsc.org</a> is an independent standards group largely drawn from the traditional public health workforce concerned with population health and community based care programs. It has largely been US-based but, in October, 2011, PHDSC decided to extend their reach to include the broader international activity and published a business case on public health needs in national health IT programs. It is working with ISO and HL7 on having public health information requirements addressed in standards. <strong>Action:</strong> IT-014 to arrange review of the PHDSC Business Case document to explore its relevance in the local environment and potential need for health informatics standards work in public health both in Australia and internationally.</td>
<td>IT-014</td>
</tr>
<tr>
<td>Topic</td>
<td>Issue/Action and Recommendations for Australia</td>
<td>Suggested responsibility &amp; alignment to IT-014</td>
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</tr>
<tr>
<td>GS1/JIC Automated data capture of patient and caregiver identifiers</td>
<td>GS1 is to lead and use its processes to work on production of a standard defining a framework within which automated identification technologies can be applied in wider identifier contexts for both healthcare providers and individuals. The deliverable will be entitled “Automatic identification and data capture (AIDC) marking and labeling – Patient and caregiver Identification”. <strong>Action:</strong> IT-014 to seek advice on implications for Australia and relevant experts to participate in this work item when NP ballot received.</td>
<td>IT-014 IT-014-02 NEHTA</td>
</tr>
<tr>
<td>WG 7 IEC 82304 Healthcare software systems</td>
<td>At the May 2011 meeting of TC 215, considerable concern had been expressed about the way that the IEC/62A medical devices community is handling the specification of standards for healthcare software that is not associated with a medical device. Their basic approach has been to require all healthcare software systems not contained in a medical device to submit to a quality regime almost identical to those used for medical devices without sufficient regard to the differences between healthcare software systems and medical devices, without involving the international software engineering standards community and with limited practical ability for those affected to participate. <strong>Action:</strong> IT-014 to monitor developments in progression of IEC 82304 and seek to get engagement by the Australian medical software community, TGA, IT-015 and the local IEC/62A mirror committee.</td>
<td>IT-014</td>
</tr>
</tbody>
</table>
5. AUSTRALIAN PARTICIPATION

5.1 ATTENDANCE DETAILS

Nine Australians attended as representatives for the duration of this ISO/TC 215 meeting.

<table>
<thead>
<tr>
<th>Attendee</th>
<th>Position (held at the meeting)</th>
<th>Funding Source</th>
<th>Working Group or Committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Richard Dixon Hughes</td>
<td>Head of Delegation</td>
<td>Standards Australia via the DoHA Funding Agreement</td>
<td>Executive Council member JIC Harmonisation, JIC Executive (as HL7 alternate) WG 8 and WG 1, inc joint WG 4, ISO/TR 14639 team meeting (Sun) Leader eHealth architecture component model work.</td>
</tr>
<tr>
<td>Heather Grain</td>
<td>Delegate</td>
<td>Standards Australia via the DoHA Funding Agreement</td>
<td>Executive Council member WG 3 (as convener), Traditional Medicine Task Force Leader of Clinical Decision Support and Mapping work items.</td>
</tr>
<tr>
<td>David Rowlands</td>
<td>Delegate</td>
<td>Standards Australia via the DoHA Funding Agreement</td>
<td>WG 2</td>
</tr>
<tr>
<td>Michael Steine</td>
<td>Delegate</td>
<td>Standards Australia via the DoHA Funding Agreement</td>
<td>WG 4</td>
</tr>
<tr>
<td>Evelyn Hovegna</td>
<td>Delegate</td>
<td>Standards Australia via the DoHA Funding Agreement</td>
<td>WG 1 and 8</td>
</tr>
<tr>
<td>Heather Leslie</td>
<td>Delegate</td>
<td>Standards Australia via the DoHA Funding Agreement</td>
<td>WG 1 and 8</td>
</tr>
<tr>
<td>Janette Gogler</td>
<td>Delegate</td>
<td>Standards Australia via the DoHA Funding Agreement</td>
<td>WG 2 and 3</td>
</tr>
<tr>
<td>David Rowed</td>
<td>Delegate</td>
<td>Standards Australia via the DoHA Funding Agreement</td>
<td>WG 1,2,3</td>
</tr>
<tr>
<td>Naomi Ryan</td>
<td>Secretariat</td>
<td>Standards Australia via the DoHA Funding Agreement</td>
<td>WG 8</td>
</tr>
</tbody>
</table>

Naomi Ryan attended from Standards Australia to provide the WG 8 secretariat.

5.2 FUNDING SOURCE SUMMARY

Nine Australians attended as representatives for the duration of this ISO/TC 215 meeting. The funding source for these delegates is indicated in the table below.
The DOHA funded delegates were selected through an independent panel process jointly with NEHTA, DOHA, HL7 Australia and Standards Australia.

5.3 AUSTRALIANS IN LEADERSHIP POSITIONS

Positions currently held by Australians within TC 215 are listed in the following table.

<table>
<thead>
<tr>
<th>Attendee</th>
<th>Position (held at the meeting)</th>
<th>Funding Source (for this meeting)</th>
<th>Working Group or Committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Richard Dixon Hughes</td>
<td>Head of Delegation</td>
<td>Standards Australia via the DoHA Funding Agreement</td>
<td>TC 215</td>
</tr>
<tr>
<td>Richard Dixon Hughes</td>
<td>Executive Council member</td>
<td>Standards Australia via the DoHA Funding Agreement</td>
<td>TC 215 Executive Council</td>
</tr>
<tr>
<td>Richard Dixon Hughes</td>
<td>Alternate Representative (HL7 Affiliates)</td>
<td>Standards Australia via the DoHA Funding Agreement</td>
<td>JIC Executive Group</td>
</tr>
<tr>
<td>Richard Dixon Hughes</td>
<td>Member (leading roadmap)</td>
<td>Standards Australia via the DoHA Funding Agreement</td>
<td>TC 215 Organization Task Force</td>
</tr>
<tr>
<td>Heather Grain</td>
<td>Convener (elected to May 2013)</td>
<td>Standards Australia via the DoHA Funding Agreement</td>
<td>WG3 Semantic Content</td>
</tr>
<tr>
<td>Heather Grain</td>
<td>Member</td>
<td>Standards Australia via the DoHA Funding Agreement</td>
<td>TC 215 Organization Task Force</td>
</tr>
<tr>
<td>Heather Grain</td>
<td>Member</td>
<td>Standards Australia via the DoHA Funding Agreement</td>
<td>Operations &amp; Harmonization Committee</td>
</tr>
<tr>
<td>Naomi Ryan</td>
<td>Secretariat</td>
<td>Standards Australia via the DoHA Funding Agreement</td>
<td>WG8 Business Requirements for EHR (and WG1 Data Structure at this meeting)</td>
</tr>
<tr>
<td>Naomi Ryan</td>
<td>Member</td>
<td>Standards Australia via the DoHA Funding Agreement</td>
<td>Operations &amp; Harmonization Committee</td>
</tr>
</tbody>
</table>

It should be noted that convenors, and heads of delegations are automatically members of the Executive Council, and that convenors, vice-convenors and secretaries are members of the Harmonisation and Operations Committee.
6. TC 215 EXECUTIVE COUNCIL

The TC 215 Executive Council comprises the TC 215 Chair, the Head of Delegation for each country, and the Convenor and Vice-Convenor of each TC 215 Working Group. Its role is to consider issues of governance and process relevant to the TC.

Meetings of the Executive Council are chaired by the TC 215 Chair and are not generally open to delegates other than the members of the Council.

A substantial proportion of the Executive Council's time at this meeting was again spent on reviewing progress by the Reorganization Task Force, building on previous work on the mission, objectives and issues and discussing actions required to implement an improved structure for TC 215. In summary, the main directions emerging from this work are:

- Support for further developing the concept of a Coordination Group that would report to the Executive Council to provide stronger overall coordination of TC215 work. It is proposed this group develop and maintain operational plans across TC 215 and oversee their delivery.

- Continuing support for hosting cross-SDO (x-SDO) work in behalf of the JIC. This would take place through a more appropriately named Cross-SDO Advisory Group (AG 3)

- Cautious support for reducing the number of "standing" work groups that oversee programs of activity back to four "cross-cutting" groups (CCGs). Each CCG would cover a clearly-specified over-arching area of work which requires permanent status. The proposed CCGs are:
  - CCG1, concentrating on modelling structures, processes and contexts that underpin specific domains (roughly equivalent to existing WG 1, with some elements of WG 2, 3 and 8)
  - CCG2, focussing on data and device interoperability (incorporating much of what occurs in WG 2 and WG 7)
  - CCG3, concentrating on standards for terminologies (excluding specific content) and aspects of ‘semantics’, e.g. decision support, metrics, user interfaces (including existing WG 3)
  - CCG4, representing ‘core culture’, and currently exists as an aggregation of a number of diverse ‘enterprise’ portfolios that deal with ‘safety’, ‘security’, ‘accountability’, ‘quality’ etc (including activities of WG 4 and PSTF).

- Vertical (or Domain) Working Groups – more closely aligned with the original ISO view of a Working Group, each handling a closely related bundle of projects – without necessarily having an on-going role once the projects are complete.

- A group focussed on business requirements (which would represent a maturing of the work being undertaken by the current WG 8 of which Australia is the Secretariat.

- Developing a supplementary agreement for TC 215 national member bodies that clarifies and encourages their involvement in managing TC 215 activities.

- The need to spell out in more detail the identity, scope and roles of all the components in the proposed new organisation, map existing activities to them and to make recommendations for adoption and implementation of the revised structure – this task is to be undertaken by the Task Force on Reorganisation and Business Planning through a series of teleconferences up to the TC 215 Plenary meeting in May 2011.
Through the senior ANSI representatives present, advice was received that variations of the term "Working Group" could be used for both the CCGs and the Vertical WGs and that it was common for ISO TCs to have standing working groups and that this situation does not necessitate the formation of separate subcommittees, rather than working groups. The reason that TC 215 has avoided

As a result of his contributing some observations on methods used by other SDOs to assess new projects against their strategic objectives, Richard Dixon Hughes was asked to convene a group to prepare information and suggestions on assessing projects against strategic drivers and report at the Vancouver 2012 plenary. The activity is to investigate possible methods of aligning the prioritisation, selection and approval of work items with TC 215 strategic objectives, including harmonisation and cohesiveness. This work be undertaken in collaboration with the TC215 Task Force on Re-organisation and Business Planning.

Other topics addressed included the practical implications of the transfer of the ISO/TC 215 Secretariat to AHIMA, management of projects that had not been progressed as originally planned (largely because of the change in Secretariat), proposed changes in internal TC 215 procedure (based on review and advice from ANSI) and greater use of ISO infrastructure, including migrating to the ISO Livelink facility as the principal means of sharing TC 215 documents and records.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Issue/Action and Recommendations for Australia</th>
<th>Recommended for action by</th>
</tr>
</thead>
<tbody>
<tr>
<td>TC 215 Executive Council Reorganization</td>
<td>Action: Richard Dixon Hughes to investigate and report at the May 2012 plenary meeting on the possible methods of aligning the prioritisation, selection and approval of work items with TC 215 strategic objectives, working in collaboration with the TC 215 Task Force on Re-organisation and Business Planning.</td>
<td>Richard Dixon Hughes</td>
</tr>
<tr>
<td>Task Force</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TC 215 Upcoming JIC Upcoming TC 215 meetings</td>
<td>TC 215 is looking to establish a 5-year meeting schedule and coordinate through JIC with other Health Informatics SDOs to minimise clashes. Having been the host in 2002 and again in 2007, it is again getting around to being Australia's turn and we certainly need to plan to be host some time in the next 5 years, which will incur some cost. Action: IT-014 and Standards Australia to agree on a date and terms on which Australia can commit to host a TC 215 meeting within the next 5 years – before the May 2012 plenary – and consider how this might be funded.</td>
<td>IT-014 and Standards Australia</td>
</tr>
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</table>

7. **JIC HARMONIZATION ACTIVITIES**

7.1 **JOINT INITIATIVE COUNCIL (JIC) – BACKGROUND**

<table>
<thead>
<tr>
<th>Australian Delegate Attendance</th>
<th>Joint Initiative Council (JIC) meeting</th>
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<tbody>
<tr>
<td></td>
<td>– Richard Dixon Hughes (participating as alternate for HL7 Affiliates)</td>
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<tr>
<td></td>
<td>– Most other Australian delegates (observing)</td>
</tr>
</tbody>
</table>

The Joint Initiative Council (JIC) oversees processes to enable common, timely health informatics standards by addressing and resolving issues of gaps, overlaps, and counter-productive standardization efforts through:

- Mutually agreed decision processes to meet needs for joint international standardization work;
• Coordinated standards strategies and plans, with the future goal of making all standards available through ISO;
• An integrated work program; and
• Focused, specific resolution of overlapping or counteracting standards within the participating SDOs existing work programs.

The standards development organisations (SDOs) that currently comprise the JIC membership are: ISO/TC 215, the European CEN/TC 251 health informatics committee, HL7, CDISC, IHTSDO and GS1. More information on the JIC may be found on the JIC website: http://www.jointinitiativecouncil.org/.

The JIC is in the process of further transformation in the way it operates, with this being the first full face-to-face meeting of the JIC leadership since it was resolved that JIC meetings held at working meetings of its member organisations would be open to any who wished to be present and observe. The JIC meeting was held from 0900-1500 on the Tuesday before the main TC 215 meeting commenced on the Wednesday. Richard Dixon Hughes participated in the JIC executive meeting in an official capacity on behalf of the HL7 international affiliates and the proceedings were observed by most other members of the Australian delegation.

In addition to the JIC itself, other related meetings that were held included:

• The Joint Initiative (JI) Open Forum. The purpose of the Open Forums is to share information through reports on joint work, reports from the JIC and reports from the Harmonization Track meetings.

Open Forum meetings are held at ISO/TC 215 meetings, HL7 WGMs and, as required, at major events staged by each of the other JIC members. On this occasion it was held between 1530 and 1700 hours on the Tuesday, immediately after the main JIC meeting.

• Joint Initiative Harmonisation Track. These meetings provide working group convenors, technical chairs and work item leads the opportunity to address balloting issues, assign leaders and expert participants to projects, consider intellectual property and other process issues in relation to both planned and in-progress JIC joint work items. Harmonisation Track meetings provide an opportunity for proposed new joint work items to be put forward for review and examination with input and feedback being provided from each of the participating SDOs.

Open to the whole community, these harmonisation meetings now take place as an additional stream of work at ISO/TC 215 meetings and continue to be constituted as an ISO/TC 215 activity (formally ISO/TC 215/AG 3), but are run on behalf of the whole stakeholder community.

The JIC Chair now rotates between the participating SDOs every year, with the Chair for 2011 being Bron Kisler from CDISC, who is continuing the work of reforming the JIC and its processes. Further reforms currently being progressed include:

• A review of the Joint Initiative Charter.
• The difficult issue of how to harmonise on-going maintenance of jointly published standards.
• Getting more effective use of JIC-sponsored Open Forums at ISO, CEN, HL7 and other meetings.

The TC 215 Secretariat also provides the secretariat for the JIC, which meant that JIC was also affected by the move of the TC 215 Secretariat from HIMSS to AHIMA in Jun/Jul 2011. Despite some initial teething problems, AHIMA appear to have grasped this role strongly.

HL7 hosts the JIC website on behalf of the JIC Secretariat. This website holds a registry of projects, inventory of policies and records of meetings and agendas but is now getting a bit behind. As more
details (including official minutes) become available it is expected that they will be posted on the JIC website: www.jointinitiativecouncil.org.

7.2 JIC OUTCOMES

The following are among the outcomes of deliberations from the JIC leadership meeting:

1. Progress in harmonising the forward program of meeting dates for health informatics standards meetings with agreement being reached that:
   - The May 2012 TC 215 (plenary) meeting will be held in Vancouver, British Columbia from 13 – 16 May, in the week ahead of the HL7 Working Group Meeting, which runs from 15 – 12 May at the same venue.
   - Tentative arrangements for the following meeting of TC 215 to be held in Vienna, Austria around 24 September should continue to be progressed
   - The JIC Secretariat (also being the TC 215 Secretariat) would attempt to populate a 5-year forward program of meeting dates for health informatics standards meetings.

2. Finalising the agenda for the Open Forum later that day, noting that there was no longer any need for the Open Forum to repeat material covered by the JIC in open session earlier in the day.

3. Noting progress of joint work in process and the proposed inclusion of new work items as reported in section 7.4 below.

4. Noting progress in the review of the JIC Charter, policy and procedures (being led by Christian Hay of GS1), in particular:

5. Suggested new arrangements for rotation of JIC chair based on an overall 4-year commitment – 1 year as Chair-elect, 2 years as Chair and 1 year as Immediate Past Chair. The rules will need to be clear on how being Chair interacts with the respective person’s representative roles on the JIC. It was suggested that the Chair’s roles would be in addition to their representative roles and that they would not be precluded from debate and discussion in their representative capacity when performing the Chair’s role.

6. Review and agreement of agenda for cross-SDO (xSDO) meetings during the TC 215 meeting in Chicago.

7. Noting problems with SDO alignment and the need for JIC and those working on xSDO harmonisation to come up with recommendations to improve handoff and ballot synchronisation for further consideration.

Some of the Australian delegation who have been involved in JIC activities since close to its inception (including Dixon Hughes, Grain and Rowlands) are seeing the increased possibility of valuable learnings, hard-fought compromises and the stakeholder imperative of effective harmonisation being lost through JIC leadership changes and these viewpoints were put on the table at the meeting. The importance of understanding the ISO and CEN rules for progression (including fast track and other less commonly exercised pathways) was also stressed.

8. Presentation and discussion of the activities that JIC had sponsored on standards access for low and middle income countries (LMICs) – as reported in section 7.4.3 below.

9. It was noted that the TC 215 Advisory Group 3 (AG 3) on Cross-SDO (X-SDO) Coordination now has the formal role previously constituted as ISO/TC 215/WG 9 and operating under the titles
"JWG" and "JWG-H". Hopefully, this is a more accurate designation and will remove most of the confusion about the role of the X-SDO Coordination Group.

10. It was agreed that there is a need for at least one meeting of the JIC by teleconference before the end of 2012, which would probably need to be in December.

7.3 JIC OPEN FORUM

<table>
<thead>
<tr>
<th>Australian Delegate Attendance</th>
<th>Richard Dixon Hughes (JIC alternate for HL7 affiliates)</th>
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</thead>
<tbody>
<tr>
<td>Heather Grain, Janette Gogler, Evelyn Hovenga, Heather Leslie, David Rowed, Naomi Ryan</td>
<td></td>
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</tbody>
</table>

The JIC Open Forum was held between 1600 and 1800 on Tuesday 18 October, following directly on from the main JIC meeting. Because the JIC meetings are now open and well attended by most of those interested, most delegates did not need an extensive update on current JIC activities and projects as these had just been discussed in some depth at the JIC meeting. Each of the SDOs provided a short update on their activities and matters that they considered to be of importance.

GS1 – presented by Christian Hay

GS1 is a global standards body with established processes and activities crossing many sectors across the entire globe with a focus on identification and supply chain enhancement (having commenced in the commercial application of barcodes). The main themes for GS1 in the health care sector are patient safety and supply chain improvement.

- In **patient safety** the focus is on improving point-of-care data capture (particularly down to the level of individual items), identification of subjects of care, and (several years out) identification of complex items such as kits and drug/device combinations.

- In **supply chain** the interest is in product authentication (serialisation at unit level), processes and messages to authenticate supply chain integrity and to enable interoperability of identification regimes between agencies.

IHTSDO – presented by Jane Millar

It was noted that an IHTSDO meeting had been held in Sydney during the preceding week. The following were noted as key themes and activities being pursued by IHTSDO:

- Implementation is becoming a major focus for IHTSDO. The first implementation showcase was part of the IHTSDO conference in Sydney, which attracted a broader audience and information on several excellent vendor products and implementation experiences was shared.

- Iceland, Malta and Finland are the three latest countries to join IHTSDO as members

- Strong steps are being taken to improve IHTSDO processes and expedite the timely maintenance of SNOMED CT. A trial of tooling and management structures for collaborative editing has started. This is seen as an absolutely essential reform with a draft of the content development process involving different levels of people being finished for review and the associated training being identified. It is planned to expand to the use of a team of 10 people by July 2012.

- David Markwell has been appointed as the new Chief Implementation Officer.
HL7 International – presented by John Quinn

John summarised the range and scale of HL7 global activities touching on a few topics of particular interest to its international partners and harmonization with other global SDOs, including:

- This is HL7’s 25th year of operations and it now has 36 international affiliates and the number continues to grow (a net increase of 2-3 per year).
- Key HL7 International products are v2.x messaging, v3 messaging and CDA, and are being increasingly being supported by tooling more closely aligned with mainstream ICT technologies. Product release cycles have been tightened.
- HL7 International currently has about 53 active work groups under four steering divisions. Domain Experts Steering Division, which has oversight of clinical and other domains has the biggest number of active work groups.
- HL7 currently has over 325 active projects.
- HL7 project management has been tightened. All HL7 work requires a TSC-approved project. Failure to file a project application and register a project results in a refusal to approve the balloting of any resulting document produced by the project, until the project is registered and approved.
- HL7 has moved to a governance model in which the Board operates at a strategic level and drives the work program through strategic initiatives. Those wishing to initiate joint work with HL7 need to be aware of the importance of mapping new work items to strategic initiatives in order to be successful and gain TSC approval.
- All normative standards require a 1-2 year period as a draft standard for trial use (DSTU) before being elevated to normative status and at least two organizations are required to have tested the DSTU before normative balloting is permitted.

ISO/TC 215 – presented by Don Newsham

Don Newsham gave a brief overview of TC 215 activity noting that:

- This was a major period of change with the TC 215 Secretariat moving from HIMSS to AHIMA. This was a complex technical job and both Lisa Spellman and AHIMA deserved great credit for a major achievement in getting the meeting together so well in such a short time.
- The TC 215 task force working on reorganization is now deeply into its activity and is engaged in implementation planning with Jeremy Thorp leading the exercise. The underlying philosophy is to change what must be changed and keep what needs to be kept.
- Current working group activities are to be re-structured into cross-cutting groups (CCGs) overseeing a range of “vertical” working group more focussed onto closely related bundles of project activity – with the option of being disbanded or suspended when the main development activity is completed.
- TC 215 leadership has been strongly focussed on the importance of producing those standards that are needed by the various countries around the world but also needs to remember and better accommodate corporate needs for standards.

CDISC – presented by Becky Kush

CDISC is moving its strategic focus back from longer-term themes in a 10-year time frame back to more immediately realisable shorter-term (4 year) strategic goals but still with the overall vision of
"Informing patient care and safety through higher quality medical research."

Specific CDISC strategic goals for 2011-2015 are in the areas of:

1. Core standards for aggregate data analysis - to achieve significant progress in the use of core CDISC standards to allow scientifically sound data aggregation and support secondary uses of research data for the purposes of scientific investigation and comparative effectiveness.

   In particular, to support collaboration through the Coalition Against Major Disease (CAMD) to facilitate the sharing of trial data in related areas (e.g. Alzheimers, Parkinsons and neurodegenerative disease).

2. Health care research data interoperability - to achieve significant progress in enabling interoperability between clinical care and clinical research, and explore expansion from bench to bedside.

   By linking these realms through standards, CDISC will follow its principles of collecting data once, using it many times, so that research informs healthcare and healthcare roof informs research.


   As its contribution in this area, CDISC has developed the CDISC-SHARE - a globally accessible, electronic library for health and research content (from CDISC standards), which will enable precise and standardised data element definitions and richer method after that can be reused within applications and across studies to improve by medical research and its link with healthcare.

   This work is supported by participants that have agreed on its value and will be developed in concert with Stan Huff at Inter Mountain and Mayo and with the outcomes of the CIMI process.

4. Therapeutic/specialty area standards - to expedite the development and rollout of new therapeutic-area or specialty standards while continuing to refine, support and educate on existing standards.

   Incorporating therapeutic area needs into existing CDISC standards would ensure consistency in data capture and analysis of therapeutic endpoints and other disease-specific data elements to address efficacy and other aspects of trials.

5. Ensure CDISC infrastructure to support the first four goals.

   This requires work in the areas of standards maintenance, legal/HR/accounting, education, strategic alliances, member relations, public relations and, most importantly of all, communications.

As part of the planning process, important lessons have been learnt by obtaining feedback from those most involved in CDISC standards committees, with some of the key feedback being:

- the need to balance innovation against specification by defining what can be supported rather than constraining a perfect solution;
- the need to learn from others who have pushed the envelope, rather than reinventing the wheel;
- to focus on the implementability of standards and their adoption rather than their development -- success is measured by adoption not production.

It was also noted that CDISC is looking to manage a robust, quality process that is far more streamlined than the one that they originally used for developing their core standards. They are also embracing the need to think outside the box, leverage the ability to work with other SDOs, grow the volunteer community and use tools such as CDISC-SHARE.
Challenge – useability and usefulness of health informatics standards

The Open Forum then explored strategic issues relating to the relevance of standards in health informatics and practical issues of harmonisation. The topic was introduced in a presentation by Prof Stephen Kay (UK) on "The useability (or not) of health informatics standards" that strongly challenged the status quo and noted commonly encountered comments of those sceptical of health informatics standardisation:

1. the time the process takes to complete the vis-a-vis the rapid change in technology;
2. the duplication, over-lap and contradictory outputs from SDOs;
3. the distance from the consumer
4. the summation of these problems in the epithets:

"the nice thing about standards is there are so many of them to choose from" and
"when you've seen one implementation of a standard, you've seen only one implementation."

Some of the themes developed during the presentation and discussion included:

- Usability and standards should be more closely related but the aspirations of standards developers not close connected with their use can easily cloud the horizon and lead to a document that is neither timely, useful or a standard. Involvement of users through "engagement and participation" is a panacea – but has it been delivered by SDOs?
- Distance from the consumer is a practical issue – and one that the JIC needs to tackle
- Standards are not and can never be the definition of a "solution". For example, the EHR communication standard has taken 26 years from the first ENV 12265 to its first systematic review as the current ISO 13606 – the underlying technologies and the proposed standard changes markedly through that time and adversely impacted both development and uptake.
- All SDO's are under increasing pressure to show value to the market.
- IHTSDO and SNOMED CT can be considered as a case study. Uptake is still problematic – the value proposition is still seen by many as a "belief".
- Usability is not just about end products but also the process. We need to apply the principles that underpin the ISO 9241-series of standards on the ergonomics of man-systems interaction to assess the usability of our products. Do we do needs analysis and apply the other key principles? By whom? and how is the assessment of usability done?
- Are the standards we produce needed? This statement itself is a fallacy – it is not right to talk about standards that are "needed". We should not be telling the public that they need a standard. But if assessed in terms an objective measure of 'usability' we would have a more suitable criterion on which to judge the potential value of proposed standards work.
- The standards community needs to focus on two types of evaluation – formative evaluation (which we do quite well) and summative evaluation (focussed on post-implementation review, which we do badly). Many ISO and CEN health informatics standards are perceived as academic exercises, rather than tools of trade to ensure safe effective implementation of health IT capability.
- There needs to be a sunset process for unused standards as well as for old standards but we often don't know when or where a standard is used or by whom.
- In Europe, the M/403 INTEROP report – indicated the requirement for evaluation and feedback on health informatics standards but the initiative to achieve this didn't seem to keep moving.
• We need to leverage research and methods outside our traditional areas as "experts". For example the use of social sciences if a standard is proposed as a solution to a coordination problem – to provide processes by which parties can recognise areas in which they can make mutual gains. Other areas include helping users to define what "usability" means for their business.

• Proponents of health informatics standardization need to market more effectively, which means identifying and satisfying market needs. Academics and standards developers are quite good at coming up with ideas but not necessarily selling them and gaining acceptance outside their own kind.

• Education on standards is critical but often absent. CDISC and HL7 have collected information on which universities teach standards but there is a need for use cases to be available on a website and materials readily available through literature research. The potential leverage of the SKMT tool and spider was noted as a possible facilitator in this area.

7.4 CROSS-SDO ADVISORY GROUP

<table>
<thead>
<tr>
<th>Australian Delegate Attendance</th>
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<tbody>
<tr>
<td>Richard Dixon Hughes (as alternate for HL7 Affiliates)</td>
</tr>
<tr>
<td>Joint Initiative Council (JIC) Harmonization Task Force – Information session &amp; open forum – Most delegates</td>
</tr>
<tr>
<td>JIC Harmonization Track – partial attendance and input from:</td>
</tr>
<tr>
<td>- Heather Grain (presenting SKMT)</td>
</tr>
<tr>
<td>- Richard Dixon Hughes, David Rowlands</td>
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7.4.1 APPROVED PROJECTS – PROGRESS REVIEWS

Activities completed

• ISO 21090:2011 Health informatics – Harmonized data types for information interchange. This was completed in 2011 (and is presently being reviewed by IT-014-09 to identify how Australia may best use this work, given that some of its concepts are beyond current practice).

• ISO/HL7 10781:2009 Electronic Health Record-System Functional Model, Release 1.1. Although the progression of this item was shepherded by the JIC, it was actually brought to fruition by using the agreement between ISO and HL7, with CEN acceptance in parallel with ISO.

• Initial set up of the Standards Knowledge Management Tool (SKMT). This tool has been developed under the leadership of Andrew Grant (CA) with input from Heather Grain (AU) and the generous support of the University of Sherbrooke in Canada. The tool is set up and the project has transitioned to the operational stage with all JIC members looking to participate.

Current JI-approved projects – progress reviews

Current work items, whose progress was reviewed in the JIC and/or X-SDO Coordination Group sessions, included:

1. Population of Standards Knowledge Management Tool (SKMT) The project is now well into the implementation phase with its repositories being partly populated with material from ISO/TC 215 with smaller amounts from HL7 and others with considerable resources being required to get data
loaded and up to date. Other members of the JIC are supportive of having their information included but resources remain the challenge.

2. **ISO 14199 The BRIDG Domain** analysis model for protocol-driven biomedical research. This was approved as a JIC joint project in January 2009, with CDISC as the lead and TC 215 collaboration being managed through WG 2. Further information is available in section 9.8 below. Harmonisation for 3-way balloting (and longer-term maintenance) between HL7, ISO/TC 215 and CDISC remains the main issue that is now being addressed via a different approach under which CDISC will be recognised as having the predominant forward maintenance role.

3. **Clinical Trials Registration and Results Reporting.** HL7/RCRIM work on this topic was approved as a JIC joint project in April 2009 with HL7, TC 215 (WG 2) and CDISC participating and Scott Getzin as the project lead. As reported in section 9.9 below, ballot materials were delayed in the handover of the TC 215 secretariat from HIMSS to AHIMA but the problem has now been identified and the work is expected to get back on track shortly.

4. **Individual Case Safety Report (ICSR).** This was approved as a JIC joint project in October 2008, with ISO/TC 215/WG 6 as the lead and strong collaboration from CEN/TC 251. WG 6 (Pharmacy) did not have sufficient notice to meet at the October 2011 meeting and the project lead, Ian Shepherd, was not available to give an update.

5. **Identification of Medicinal Products (IDMP).** This was approved as a JIC joint project in June 2009, with ISO/TC 215/WG 6 as the lead and strong collaboration from CEN/TC 251. WG 6 (Pharmacy) did not have sufficient notice to meet at the October 2011 meeting and the project lead, Ian Shepherd, was not available to give an update.

6. **ISO/HL7 10781 EHR-S Functional Model R2.** This was approved as a JIC joint project in October 2009 with HL7 lead (Gary Dickinson, John Quinn and Don Mon) in collaboration with ISO/TC 215/WG 8.

Gary Dickenson presented on the progress that has been made. Inputs have been taken into account from many sources including comments and requirements deferred from the work on the current Release 1.1 (R1.1), functional profiles being used in the US, Canada and Europe, the ISO and CEN NP ballots for Release 2; the PHR-S FM; the HL7 EHR Interoperability and Lifecycle models; and other related HL7 standards. The ballot draft was in the final stages of finalisation with WG 8 proposing to move forward to ballot it directly. (See further report at section 8.10 below)

7. **Automatic identification and data capture standard patient ID and Care Giver ID.** This was approved as a JIC joint project in May 2011 with GS1/Health lead (Christian Hay). See report at section 7.4.6 below for more details. WG 1 will be tracking this work in ISO/TC 215.

8. **Enabling participation and access by low and medium income countries (LMIC) to health information and technology standards.** Whilst not aimed at a standard as such, JIC agreed to sponsor activity in this area at its May 2011 meeting. An update is provided in section 7.4.3 below.

**Potential JI-projects pending approval**

The following were noted as potential JI projects presented at previous JIC meetings, which are still awaiting formal approval by the JIC, pending further progress or information being provided:

1. **ISO 13972 Quality requirements and methodology for detailed clinical models.** Proposed by William Goossen on behalf of that TC 215/WG 1 at the May 2011 meeting, the JIC was awaiting confirmation of the standing of the item within TC 215 and advice as to whether any other SDO...
wishes to participate. The work item was covered extensively in joint sessions of WG 1 and WG 8 – see section 8.6 below.

2. Business requirements for a syntax to exchange structured dose information for medicinal products. This has been proposed to JIC by ISO/TC 215/WG 6 (Ian Shepherd). Further information is awaited.

3. Data types implementation guide (in relation to specific use cases). Heather Grain is the proposed project lead and is still in the process of developing a more detailed outline of the item on behalf of ISO/TC 215/WG 3

7.4.2 PROPOSALS FOR NEW JOINT WORK

The following items/issues were raised for consideration and potential progression via the JIC:

1. *IEC 82304-1, Safety aspects of healthcare software systems – Part 1: General requirements.* Patty Krantz, Chair of TC 215/WG 7 attended to present the items but was unable to because of scheduling issues. She forwarded a copy of her proposed presentation. Richard Dixon Hughes spoke to Australian concerns about the way in which this joint work appears to be being progressed unilaterally by the medical devices community without broader input from the health software and software engineering communities.

There is potential interest from HL7, CEN and ISO, with consideration needing to be given to effective broadening of the use and requirements beyond the medical device approach that was proposed in May 2011 and rejected by TC 215. This topic is reported in more detail in section 7.4.7 below.

2. EHR Clinical Research Functional Profile. This was raised as a matter that JIC might need to review with the respective SDOs as it appeared that the project as balloted in TC 215 varied significantly from what HL7, CDISC and several TC 215 members had understood to be the basis on which the project was originally proposed and only a few (including Australia and Canada) had picked up the change. As covered in section 8.4 below, the critical issue the need for any functional model in this area to build on the established ISO/HL7 10781 EHR-S FM framework.

3. *ISO/TR 17991 Guidance on standards for enabling safety in health software.* As outlined in section 8.7, this work was originally put forward at the May 2011 meeting if TC 215 and the outcome of the successful NP ballot reviewed in joint session with the relevant TC 215 working groups. Other SDOs have expressed interest in considering joining the project, pending further review. The potential for other SDO standards to be considered as part of the review and analysis was seen as important, irrespective of whether the project is conducted as a joint project or not.

4. *ISO 13940 System of concepts to support continuity of care* (Contsys). The current joint ISO/CEN Contsys project involves revision and update of existing work originally undertaken by CEN. The lead is Nicholas Oughtibridge (for TC 215/WG 3) although his role on the project needs to be re-confirmed following staff changes in the UK NHS.

As reported in section 8.8 below, there is growing Australian interest in this project and concern that HL7 should be a participant, although HL7 has indicated that they would need to be convinced that it needs to progress from an ISO/CEN project to a JIC project with their involvement. Bernd Blobel volunteered to assist JIC members understand how to navigate these specifications.
7.4.3 JOINT E-HEALTH STANDARDS INITIATIVE FOR LMICs

At the request of various interested parties, the JIC had acted as the convener of a working meeting on enabling access to eHealth standards and participation in eHealth standardization activities in low and medium income countries (LMICs). The meeting was held in Geneva on 29 and 30 September 2011, with the following people and organisations being among those present:

- Bron Kisler (Chair JIC, CDSISC)
- Robert Stegwee (JIC, CEN/TC 251)
- Don Newsham (JIC, ISO/TC 215)
- Jean-Eric Slot (IHTSDO)
- Peter Murray (IMIA)
- Lincoln Moura (IMIA)
- Beatriz de Faria Leao (ISO/TC 215/PHTF)
- Samuel Cheburet (Kenya Ministry of Health)
- Ramesh Krishnamurthy (WHO)
- Mary Kratz (Pepfar)
- Christian Hay (JIC, GS1)
- Mary Lou Pelaprat (ISO/CS & /TC 215)
- Elizabeth Keller (JIC, ISO/TC 215)
- Jane Millar (JIC, IHTSDO)
- Antoine Geissbuhler (IMIA)
- Colleen Brooks (Singapore MOHH)
- Chris Seebregts (South Africa)
- Sayave Gnoumou (Cameroun & African Union)
- Patrick Whitaker (WHO)

The workshop had reviewed requirements, the types of standards that LMICs considered useful, opportunities, barriers to participation and access, and potential stakeholders. The principal outcomes from the meeting were a strategy for enabling access to standards for LMICs, as follows:

### Strategy for enabling access standards for LMICs

1. **Raise awareness and education in standards within LMICs**
2. **Regional standards collaborative groups for LMICs**
   - LMICs consider forming regional eHealth standards collaboratives
   - SDOs to consider meetings in LMIC countries or in conjunction with collaboratives
3. **Infrastructure & Governance for Standards in LMIC**
   - Combination of measures aimed at increasing local capabilities and local policy support, mutual sharing and of expertise and capability and improving access to and managing intellectual property
4. **Source funding for LMIC increased participation in standards**
   - Based on getting NGO and donor support

The proposed next steps are proposed as:

1. Socialising the Geneva outcomes (strategies, tactics, stakeholder roles, etc), including the presentations at the Chicago meeting and discussion with organisations such as HL7.
2. Develop communications summaries of the LMIC initiative.
3. Explore other opportunities for discussion – including through HL7 WGM in January, HIMMS (in February) and a possible Africa meeting in mid-2012.
4. Create a plan or “LMIC Standards Awareness Roadmap”.
5. Select lighthouse project(s) from LMIC countries that show quick wins and demonstrate alignment with a strategy to build awareness of standards.
6. Approach donors after plan the plan has been developed.

7. Continue to engage key stakeholders – to build critical mass and create a tipping point on taking action on standards for LMICs.

During discussion it was noted that IMIA’s working groups – specifically ‘Education in Health/Medical Informatics’ and ‘Standards in Health Informatics’ - can help build capacity for the JIC initiative in LMICs – as IMIA penetration in LMICs is significantly larger than ISO or other SDOs.

Relevance to Australia

It is suggested that Australia observe but not seek to become actively involved at this point, noting that this activity is not directly aimed at standards work and is closely aligned with the activities of the Public Health Task Force (see section 7.4.4 below). Nevertheless, if requested, Australia should be prepared to share relevant information and consider any request for assistance or mentoring of LMICs in our region.

7.4.4 PUBLIC HEALTH TASK FORCE (PHTF)

In the report on the ISO/TC 215 plenary meeting in May 2011 it was noted that TC 215 had approved the formation of a Task Force on Public Health Informatics (PHI-TF), now more commonly referred to as the Public Health Task Force (PHTF) and that the individuals involved, the motivations, purposes and activities were similar to those put forward in support of some other current standards work, notably the ISO/TR 14639 Capability-based eHealth architecture roadmap, ISO/TR 11165, which is putting the WHO Health Metrics Network (HMN) framework into an ISO context, and the joint eHealth standards to make eHealth standards more readily available to low and medium income countries (LMICs). A common theme to all these proposals has included leveraging NGO support and donor funding to progress all of these activities in parallel as interdependent activities.

The current operational definition of "Public Health" encompasses almost all and any aspect of health care provision, as follows:

"the science and art of preventing disease, prolonging life and promoting health through the organized efforts and informed choices of society, organizations, public and private, communities and individuals" (1920, C.E.A. Winslow).

Since its formation at the previous TC 215 meeting, the PHTF has been working on its scope and terms of reference. A presentation was given, followed by discussion, with the following being noted:

- One of the key drivers for international standards work in this area is that many guidelines are provided by different organisations supporting public health initiatives and each has its own reporting requirements. Consequently there is a need to harmonise these reporting requirements to ease the burden of low and medium income countries (LMIC).

- An assertion that TR14639 Capacity-based e-health architecture roadmap will form the foundation for the PHTF strategy. This combination was referred as ‘autocatalytic’ as each strengthens and supports each other.

- The purpose of the PHTF is defined to be:

  "To provide a forum for ISO delegates and invited experts to collaborate on health information standards activities for public health, especially LMIC"
The proposed deliverables from the PHTF’s activities are to:

- Identify which standards are necessary to support and facilitate public health information needs (noting that ISO/TR 14639 forms the basis for the PHTF strategy [at least to the extent that it defines the applicable standards])
- Propose methods to provide LMIC access to public health standards
- Develop rationale for PHTF and host organisations to be included in xSDO activities
- Propose the methods to establish liaisons with other Technical Committees, donors IMIA, IHE, PHDSC and other key organisations such as the US-CDC
- Provide guidance and directions for LMICs to develop local health informatics committees, using/leveraging public health information standards as a starting point.

Discussion focussed on the best framework under which this group should operate, including provision of a secretariat and funding sources. It was noted that its activities were potentially broader than the scope of TC 215 but complementary to TC 215’s role as a standards developer. The conclusion was that the PHTF could commence under an initial ISO or JIC auspice to kick-start it but with the aim of proceeding under a more sustainable model in the future. IMIA and PHDSC expressed interest in participating and collaborating. Australia highlighted some of the anomalies in scope and roles between the PHTF activity and those of TC 215 (as an ISO technical committee developing standards) and JIC (as an unconstituted group, which operates through its members, rather than in its own right).

It was agreed that there is a need to identify relationships and boundaries for all stakeholders. The JIC is to develop the business case, another organisation is yet to be identified to provide secretariat and to drive this work item.

Relevance to Australia

The scope of the PHTF activity is extremely broad and is not primarily aimed at producing a standards deliverable. Nevertheless, it is presented as complementing ("being auto-catalytic with") several items on the ISO/TC 215 work program and, in presentations by the TF, its activities are increasingly being conflated with the completion of those work items, despite their being managed by WG 8. It is suggested that Australia observe but not seek to become actively involved in the broader agenda of the at this point, other than to the extent that the PHTF becomes the vehicle to complete existing standards work items (if that occurs). Nevertheless, if requested, Australia should be prepared to share relevant information and consider any request for assistance or mentoring of LMICs in its region.
### Public Health Task Force (PHTF)

At the May 2011 meeting, a Public Health Task Force (PHTF) was formed with an extremely wide scope. The PHTF is being used as a vehicle to promote and seek financial support for a range of standards activities and policy changes – particularly to benefit low and middle income countries (LMICs). How the longer-term activities of the PHTF relate to TC 215 as a standards committee is somewhat unclear but there have been some moves to use it as a vehicle to progress work on several current WG 8 work items.

**Action:** IT-014 to monitor PHTF developments but not seek to become actively involved other than participating to the extent that the PHTF becomes the vehicle to complete existing standards work items and considering any request to share relevant information or to provide assistance or mentoring for LMIC standards work in our region.

### PUBLIC HEALTH DATA STANDARDS CONSORTIUM (PHDSC)

Under the auspices of the PHTF, a separate presentation was given by Walter Suarez and Anna Orlova on behalf of the Public Health Data Standards Consortium (PHDSC) – www.phdsc.org.

The organisation has been operating for some years based on volunteer engagement among the traditional public health workforce concerned with population health and community based care programs. It has largely been US-based, but in October, 2011 PHDSC have decided to extend their reach to include the broader international activity.

They have recently published a document entitled ‘Business Case for: Role of Public Health in National Health Information Technology Standardisation’ and are actively working with HL7 on extending the HL7 functional model standards to encompass public health needs.

During discussion it was suggested that their activity and experience may inform the work of the Public Health Task Force work.

**Relevance to Australia**

Australia could benefit from harmonised outcomes from this work and should keep a close watching brief as it evolves. The PHDSC Business Case document should be reviewed to explore its relevance in the local environment.

### Public Health Standards Needs

The US-based Public Health Data Standards Consortium (PHDSC) – www.phdsc.org is an independent standards group largely drawn from the traditional public health workforce concerned with population health and community based care programs. It has largely been US-based but, in October, 2011, PHDSC decided to extend their reach to include the broader international activity and published a business case on public health needs in national health IT programs. It is working with ISO and HL7 on having public health information requirements addressed in standards.

**Action:** IT-014 to arrange review of the PHDSC Business Case document to explore its relevance in the local environment and potential need for health informatics standards work in public health both in Australia and internationally.
7.4.6 PATIENT/CAREGIVER IDENTIFICATION

All six SDOs in the JIC have been jointly involved in progressing activities based on wider promulgation and acceptance of the GS1 work on patient ID and caregiver ID under the project title “Automatic identification and data capture (AIDC) marking and labeling – Patient and caregiver Identification”.

Having been approved as a work item by all 6 JIC SDOs and now needs to be moved forward as NP with a view to work being led by GS1 under its rules (i.e. GSMP), with experts from other SDOs being invited to join the GSMP WG.

Once phase one of the work is completed under the auspices of GS1, the result is to be transcribed into an ISO Technical Specification.

Relevance to Australia

Australia should be participating actively in this work as it evolves. There is a need to understand how Australian HPIS and IHI’s can be accommodated in such a framework.

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<th>Topic</th>
<th>Issue / Action / Recommendations for Australia</th>
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<tr>
<td>GS1/JIC Automated data capture of patient and caregiver identifiers</td>
<td>GS1 is to lead and use its processes to work on production of a standard defining a framework within which automated identification technologies can be applied in wider identifier contexts for both healthcare providers and individuals. The deliverable will be entitled “Automatic identification and data capture (AIDC) marking and labeling – Patient and caregiver Identification”.</td>
<td>IT-014 IT-014-02 NEHTA</td>
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7.4.7 IEC 82304-1 HEALTHCARE SOFTWARE SYSTEMS

The potential application of medical device regulatory regimes to computer software being used in health care environments continues to be an issue within the TC 215 community and the medical software industry in Australia.

In particular, many in the TC 215 community remain concerned about the approaches being pursued in the proposed international standard IEC 82304-1 Healthcare software systems – Part 1: general requirements. This project has arisen from SC62A Joint WG7 within the IEC (International Electrotechnical Commission) and is meant to be being progressed as a joint project in formal liaison with ISO/TC 215.

The work was originally approved by IEC ballot in February 2011, was discussed by TC 215 at its May 2011 meeting in Kuopio and has recently been put to ballot for approval by ISO/TC 215 as a joint work item. None of the concerns expressed by TC 215 in May were reflected in the ISO/TC 215 ballot documentation.
The standard is proposed to apply to "healthcare software systems (HS system)" , which is defined as:

"A software system that is not a component of medical electrical equipment or a medical electrical system, and that is intended by its manufacturer to aid in:

(a) diagnosis, treatment, or monitoring of a patient; or
(b) compensation or alleviation of disease, injury or disability"

Paradoxically, the standard will apply to products that are delivered solely as software but it does not apply to software that is a component of medical electrical equipment (as this is already captured elsewhere in the medical devices regime).

The standard is intended to apply to the design, manufacture and installation of healthcare software systems, with the principal operating provision being that a risk management process complying with most elements of the ISO 14971:2007 medical device risk management standard shall be performed for healthcare software systems. There is next to no tailoring to meet other needs. The proposed new standard is applied by taking almost all references to the term "Medical device" in ISO 14971 and reading it as a reference to an "HS System". The proposed normative references include:

- ISO 14971:2007, Medical devices – Application of risk management to medical devices
- IEC 62304:2006, Medical device software – Software life cycle processes
- IEC 62366:2007, Medical devices – Application of usability engineering to medical devices

Australia had voted negatively in the recent NP ballot on IEC 82304.

Patty Krantz, who has just taken over as the convenor of ISO/TC 215/WG 7 Devices (and is also liaison to ISO/IEC 62A/JWG 7 which is responsible for managing this work item) had prepared a presentation for consideration at the x-SDO Coordination Group but was unable to give it due to scheduling problems. There was very brief discussion as the x-SDO session closed and some of the Australian concerns were introduced. Ms Krantz agreed to provide a copy of her proposed presentation for information and this was forwarded promptly.

As Australian Head of Delegation, Richard Dixon Hughes, communicated with Ms Krantz by return email indicating strong concern at the way in which this work item has been handled and the way it seems to be developing in absence of broader input from those with a primary interest in healthcare software outside the medical devices community. Against this background, the following were the main points raised:

- The lifecycle process requirements for HS Systems refer heavily to IEC 62304:2006 Medical Device Software- Software Life Cycle Process. This was not considered to allow sufficient flexibility for the much wider range of software engineering techniques used more generally for health software outside a medical device.
- An effective approach needs to have wider applicability to any type of software development and to cover both bespoke and other types of software developments.
- The proposed approach had already been rejected when discussed by a well attended meeting of relevant working groups in TC 215 and it was understood that appropriate changes to the project proposal would be made; however, this did not happen and the TC 215 ballot documentation reflected the original approach (the reason being given by JWG 7 that the unacceptable approach had already been approved in the earlier IEC ballot and could therefore not be changed).
- The group leading this work has a position within the IEC committee hierarchy that is scoped with standards for medical devices but this proposed standard explicitly excludes software used in
medical devices. The rationale appears to be that the medical devices community is seeking to control the space to ensure that they do not have to face a software quality regime that they do not control, even if this makes much of the health software industry uncompetitive.

- All of the proposed software "experts" (even those from within TC215) are in the devices area, rather than from more general areas such as EHR/PHR, diagnostic, medication management, identification management, inventory/supply, biosurveillance, clinical decision support, specific care settings etc
- Apart from the liaison with TC 215, all the proposed liaisons are with IEC and ISO committees relate to safety equipment used in health settings, rather than the safety of software; the ISO/IEC expert committees related to software and systems engineering and software quality are notably absent.
- The standard contains hardware-related display requirements and conformance tests which are out of scope and has limited capacity to adapt to emerging and innovative technologies already being used with mobile devices – risking adverse consequences if the new standard becomes the basis for regulating healthcare software in various countries.
- Most meetings of the groups working on this take place out of cycle for TC 215 and HL7, which makes participation by those already engaged in health software standards difficult.

An appropriate standard in this area is clearly required because of the growth of regulation covering software as a medical device and it is desirable to avoid a battle and find a way to do this that recognises that this has much wider impact in the healthcare software industry than the medical devices industry. IEC's JWG7 needs encouragement to take much greater steps to actively accommodate other groups - including planning to meet regularly at accessible times at TC215 and HL7 with no more than a few meetings at medical devices meetings not regularly attended by TC215 experts.

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<tr>
<td>WG 7 IEC 82304</td>
<td>At the May 2011 meeting of TC 215, considerable concern had been expressed about the way that the IEC/62A medical devices community is handling the specification of standards for healthcare software that is not associated with a medical device. Their basic approach has been to require all healthcare software systems not contained in a medical device to submit to a quality regime almost identical to those used for medical devices without sufficient regard to the differences between healthcare software systems and medical devices, without involving the international software engineering standards community and with limited practical ability for those affected to participate. Action: IT-014 to monitor developments in progression of IEC 82304 and seek to get engagement by the Australian medical software community, TGA, IT-015 and the local IEC/62A mirror committee.</td>
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8. WG 1 DATA STRUCTURE AND
WG 8 BUSINESS REQUIREMENTS FOR EHR

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<tr>
<th>Australian Delegate Attendance</th>
<th>Heather Leslie</th>
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<td>Evelyn Hovenga</td>
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<td>Richard Dixon Hughes</td>
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<td>Naomi Ryan (WG 8 secretariat)</td>
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<tr>
<td>Occasional attendees for selected topics:</td>
<td>Heather Grain, Janette Gogler, David Rowlands, David Rowed</td>
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8.1 GENERAL

The WG 1 (Data Structure) program was held jointly with WG 8 (EHR Business Requirements) with the chair alternating between convenors.

Working Group 1 is chaired by Dr Stephen Kay (UK).

Working Group 8 is chaired by Dr Marion Lyver (Canada). Standards Australia is currently providing Secretariat services (Naomi Ryan).

There is currently no Secretariat for WG1, which is affecting communication between members. Naomi Ryan (AU), head of the WG 8 Secretariat agreed to support both WG 1 and WG 8 for this meeting and was thanked by both chairs for her efforts.

Combined attendance at WG1 and WG 8 was 37 from 13 countries which included liaisons from WHO (by teleconference for key topics), Public Health Data Standards Consortium (PHDSC), Health on the Net (HON) and the International Medical Informatics Association (IMIA)

Some delays in documents progressing were noted as a result of the change in TC 215 Secretariat and associated administrative processes and online tools. A goal for this meeting was for the Secretariat and Work Group members to identify the position of each current work item and any needs for action to progress it.

8.2 STANDARDS PUBLISHED AND IN PUBLICATION

ISO TR 14292 – Personal Health Records – Definition Scope and Context has been submitted for publication but this has been delayed due to the transition of Secretariat from HIMSS to AHIMA

8.3 ISO 13606 EHR COMMUNICATION

As decided at the last meeting in May 2010, it is desirable that all five parts of the 13606-series of standards be aligned (with Part 1 already having passed systematic review) and it is proposed that a work item will be raised for all parts of this international standard to be reviewed together in 2012.

It has also been recognised that there is no definitive implementation guide to ISO 13606 and that, without this, different implementations of the standards will vary and make interoperability and consistency difficult to achieve.

Relevance to Australia

In Australia, there has been considerable interest in the ISO 13606-series of standards on EHR communication, which are closely aligned with openEHR technology.
The systematic review of the ISO 13606-series represents an opportunity for Australia to put forward constructive changes to re-align these standards to be closer to the openEHR specifications from which they originated some 7 years ago and to include some of the learnings from the subsequent implementation-driven development of openEHR. Australia had significant comments along these lines that were too late for inclusion in the first generation of ISO 13606 and which, if adopted, would enhance the value of the standards and align them better with the way they are actually being implemented.

To have maximum impact, Australia will need to prepare suggestions for the review and alignment as well as keep a watching brief on this work. Future development of this standard may include some of the learnings from subsequent implementation-driven development of openEHR.

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<tr>
<td>WG8</td>
<td><strong>ISO 13606</strong> Electronic health record communication</td>
<td>At the May 2011 meeting, it was agreed that all 5 parts of ISO 13606 should be reviewed together as a bundle and a New Proposal (NP) submitted for systematic review at that time in May 2012. Action: IT-014-09 to monitor and prepare to become involved in systematic review of all ISO 13606 documents in May 2012 and consider adoption into Australia.</td>
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### 8.4 EHR CLINICAL RESEARCH PROFILE

A recent NP ballot approved work commencing on an EHR Clinical Research Profile. Concern was expressed by Australia, Canada and others that the work item, as proposed, is planning to base the profile on the emerging, non-standard EuroRec specifications, rather than the existing International Standard, ISO 10781 EHR System Functional Model (EHR-S FM) and subsequent HL7 functional profiles applicable to research. US interests had originally assumed that the work would be based on ISO 10781 or the HL7 EHR-S FM itself and had abstained from the voting due to time pressures but became concerned when Australia explained the reasons for us having voted against the item. This concern was noted by the JIC, where CDISC also indicated strong interest and it was resolved that task force will present a proposal for a harmonised way forward at next meeting in Vancouver.

**Relevance to Australia**

Australia has an increasing interest in information interchange to support clinical research, the promotion of International Standards over proprietary regional approaches and needs to encourage communication, collaboration and re-use of existing profiles among those that will be participating in this work and should keep a close watching brief on developments to inform further inputs.

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<tr>
<td>WG8</td>
<td><strong>NP EHR Clinical Research Profile</strong></td>
<td>Australia recently voted against this work because of incompatibility between the existing HL7 Clinical Research Profile based on the existing international ISO 10871 EHR-S Functional Model standard and this proposal to base the new standards on the non-standard EuroRec specifications. A close watching brief is being maintained on this work, which was also referred to JIC. Action: IT-014-09 to maintain a close watching brief and promote a unified approach in going forward as an ISO standard.</td>
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</table>
8.5 ISO TR 14639 CAPACITY-BASED EHEALTH ARCHITECTURE ROADMAP

This technical report comprises two parts:

- ISO TR 14639-1 Health Informatics - Capacity-based e-health architecture roadmap – Part 1: Overview of national e-health initiatives; and

The report builds on lessons from many countries and was largely inspired by experience with the Health Metrics Network (HMN) activities sponsored by the World Health Organization (WHO). This work has been motivated in part by a recognition that countries vary in terms of readiness and resources for health system strengthening, with the expectation that it will help to provide the tools needed for policy-making, strategic planning and eHealth architecture development for robust and appropriate country HIS.

Australia is one of the cornerstone contributors to this part, which was passed without opposition in the recent ballot to proceed to publication, which closed in July. The meeting reviewed the outcome of the ballot and discussed the proposed disposition of comments. It will be submitted for publication after the expert group responsible for its preparation checks the amendments arising from accepted comments.

Richard Dixon Hughes is one of the original authors of Part 2, a first draft of which is approaching around 50% completion. The meeting reviewed at some length the extent of work completed to date, noting gaps and the need for more authors to volunteer. Specific suggestions for work needing to be done included:

- Suggestions that a profile of an Enterprise View should be developed - to map from WHO’s HMN Framework to eHealth Architecture framework (Parthenon diagram) and on to the more detailed maturity statements in Part 2 of ISO TR 14639 and that this be made available via the HiWiki.
- Work is required to map the HMN Framework assessment tool indicators and metrics to the eHealth Architecture infrastructure and maturity model and ensure that they are mutually complete and consistent.
- Domain requirements – a lot still to be done, authors in specific domains are required especially to develop the maturity statements.

Given the potential overlap and synergies between the work streams and some leadership roles, the relationship between TR 14639, the Public Health Task Force (PHTF), the Standards Knowledge Management (SKM) framework and other work was discussed with the following being noted:

- TR 14639 forms basis for PHTF strategy
- TR 14639 and PHTF are ‘autocatalytic’ – they strengthen and support the other
- There is potential for integration of TR 14639 and the a and hiwiki.org
- TR 14639 Part 2 will complement and support the more general requirements of the proposed ISO/TR 16555 Health Informatics - Framework for National Health Information Systems, which is based on systematised production of measures originally defined for the WHO Health Metrics Network.
Relevance to Australia

It is pleasing to see that this work has been extended to include any and all levels of maturity instead of focusing on low income countries only. Australia is in a position to support and mentor this work and the implementations that might arise based on it.

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<td>WG 8</td>
<td>TR 14639 Part 1 provides an overview of several national ehealth initiatives (with a focus on Australia, Brazil, Kenya, Canada and India) The document has been completed, accepted and is in the process of being finalised for publication</td>
<td>IT-014-09</td>
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<td><em>Action: IT-014-09 to advise parties that have already expressed interest in the document of its publication, when that occurs.</em></td>
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<tr>
<td>WG 8</td>
<td>Many contributors/editors have been involved in developing this document (TR 14639 Part 2) and more detailed contributions now exist for about half the sections. Completion of draft is now expected in the first half of 2012 (with Richard Dixon Hughes of Australia being one of the authors).</td>
<td>IT-014-09</td>
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<tr>
<td>Capacity-</td>
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<td><em>Action: IT-014-09 to monitor progress, review the document and consider contributing expert information to other sections of the draft document.</em></td>
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<tr>
<td>based eHealth architecture roadmap Part 1</td>
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<td>Capacity-</td>
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<tr>
<td>based eHealth architecture roadmap – Part 2: architectural components &amp; maturity model</td>
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8.6 ISO 13972 QUALITY REQUIREMENTS AND METHODOLOGY FOR DETAILED CLINICAL MODELS

It was noted that at the previous TC 215 meeting in May that there had been some issues about progression of the various parts of *ISO 13972 Quality requirements and methodology for detailed clinical models*.

Contrary to advice provided by a representative of ISO/CS at the previous meeting (which indicated that the work item would need to be withdrawn and re-submitted as an NP), the ANSI representative at the meeting advised that the maximum time allowed for progress on Part 1 was due to expire in January 2012 and that an extension should be sought from ISO/TMB on the basis that the current document would be put out for ballot as a CD. This approach was subsequently confirmed by TC 215 in the final plenary session.

It is also intended that the Part 2 document will be submitted to ISO secretariat in the near future for distribution as an NP/CD ballot.

Meeting Discussion and Conclusions:

The majority of three sessions/quarters, over two days, were set aside for discussions on the ISO 13972 Detailed Clinical Model (DCM) quality standards, most specifically on Part 2. This was not as effective as it could have been because, prior to the meeting, there had been a lack of access to the current draft standard documents by all except the expert group working closely on their drafting.

During discussions, it was agreed that:

- The focus of this standard is detailed clinical models at the conceptual level, not models at the more detailed logical level of the RM-ODP hierarchy.
• All references to ISO 21090 data types will be modified and treated in a similar way to references to terminology, that is, by explicitly stating the data types that have been used in each detailed clinical model.

This allows for use of ISO 21090 where desired, but allows some flexibility given current discussions about the use and profiling of 21090 data types in the Clinical Information Modelling Initiative (CIMI) work and the Resources for Healthcare (RFH) proposal currently within HL7, and to ensure that the data types will be useful not only for exchange but also for EHR persistence.

It was noted that external Korean research material related to detailed quality measures and metrics that was to be included in Part 1 and/or Part 2 had not been made publicly available by the time of the meeting. The meeting felt that taking a document focussed on this material to ballot without any indication of the content was not defensible, and it was proposed a completely separate work item be developed to focus on the framework that might apply these quality criteria and metrics to the development, collaboration and governance of conceptual DCMs. This separate work item will be developed and submitted to ISO as a NP in the future. In this way additional time will be available for the quality criteria/measures that are currently part of a Korean research project to be made publicly available. References to Quality criteria or measures will now be removed from Parts 1 & 2.

The description of scope for both parts of ISO 13972 was modified, especially in terms of removal of quality statements.

**Next steps**

As the draft Part 1 document had already been submitted for distribution by the ISO Secretariat for CD ballot as per the resolutions agreed in Kuopio, it will have to proceed in its current form, although appropriate explanatory information will need to be added to the ballot documents to explain the anticipated changes. The modifications required to take into account the proposed NP will be added to Part 1 after the CD ballot has been completed, at the time of comment reconciliation.

Part 2 of the draft document will be modified to include the change of scope and to remove all references to quality criteria/measures by the end of October and submit it to the ISO secretariat for distribution as a CD ballot.

**Issues and concerns**

Communications between the expert group for this draft standard has been less than adequate, with only one teleconference in three years, and occasional email communication from the team leader William Goossen. Australian experts have provided advice via email when requested, but often that has not been acknowledged or if a dialogue commences, there has often been misunderstanding. Hence, some three years since the commencement of this NP, the Australians in the expert group are still seeking agreement about the nature of the standard documents being developed in order to determine their impact on the national DCM approach. It has been a very frustrating process, but hopefully this has largely been resolved with this meeting.

The quality of the current draft standard documents that will be distributed soon as Committee Drafts for ballot is generally considered poor, with inconsistent language, a mixture of informative and normative statements. It will take a considerable amount of effort and time to enhance the documents to a level that will be suitable for international publication.

There is considerable confusion internationally regarding DCMs and their nomenclature with the conceptual DCMs being described in this draft ISO standard being quite different to the NEHTA library of logical models, also named DCMs.
Work on this standard appears to be driven by isolated activity with its content appearing to be currently applicable only to the work of one isolated group in the Netherlands. Unfortunately this has only become clear after three years, during this meeting. The focus in the standard on modelling at the conceptual level is in contrast to the development of DCMs at a logical level – with more than 20 collections of such models now being available which could be considered as candidates for logical DCMs.  

Examples of logical models in Australia include those being developed and published within NEHTA – starting with archetypes in the Clinical Knowledge Manager (CKM) - [http://dcm.NEHTA.org.au/ckm/](http://dcm.NEHTA.org.au/ckm/). These are being verified by the Australian eHealth community (including clinical review) and then published in a NEHTA-specific format as Detailed Clinical Models (DCMs) and aggregated into Structured Content Specifications.

Achievability and Sustainability: The work being done on conceptual models in The Netherlands is apparently being used in some implementations. To implement the approach, conceptual DCMs are being hand-built using Word documents and/or Excel spreadsheets, with no formal community review or validation process currently in place. It is not clear what form the logical expressions of these conceptual models take – possibly either HL7 models or archetypes.

In order for these conceptual models to be developed on a large scale and transformed to logical models en masse (as claimed to be supported by the draft standard), a huge resource will need to be dedicated to researching and developing each conceptual model; processes and/or tooling would need to be developed to verify the correctness and appropriateness of the models; tooling would be needed to create the logical models by transformation; and to test the resulting models to ensure that the transformation has been performed appropriately and that the resulting models are safe and fit for use. Few if any of these resources are understood to be currently available. In terms of future likelihood of success and sustainability, the resources required in terms of human effort, funding and tooling is likely to be very large, with very little of the required capability currently established.

**Alternative developments – Clinical Information Modelling Initiative (CIMI)**

The theory behind the development of conceptual detailed clinical models is that if the conceptual models are designed, developed and agreed once, then it may be possible to transform each of these conceptual models to any or all of the logical models in a consistent manner. This is certainly appealing in an academic sense, but because of the huge difference in logical reference information models, and variability in modelling approaches and concept granularity, direct transformations cannot be assumed, and very much remain in the research domain.

Experienced technical experts have expressed considerable scepticism that the transformations proposed by the principal authors of this draft standard can actually be carried out safely in practice due to differences in concept granularity and reference model constraints.

Alternative approaches have been explored in an ad hoc way for some time, and have recently become more prominent through the Clinical Information Modelling Initiative (CIMI). The CIMI remit is to determine a single modelling ‘source of truth’, that will become the common basis for clinical modelling practice and potentially to enable transform directly from one logical modelling formalism to another e.g. openEHR archetype to HL7 RIM artefact, in a consistent and prescribed manner, effectively bypassing the need for a conceptual model. It is anticipated that decisions on the CIMI’s preferred reference model, data types and modelling formalism will be made in a face-to-face meeting in Europe during November 29 - December 1, 2011. This approach may be considered safer as, in this way, the
relationship between model reference models is well known and documented and how to manage each part of the transformation can be clearly described, including which parts can be automated and which parts need to be manually managed.

Relevance to Australia

Despite voting negatively for this item at the NP stage, some 3 years ago, Australia currently has four experts participating in the development of the draft standard as our experience in this area is internationally recognised – especially through initiatives in the international openEHR community, and more recently within the NEHTA Clinical Information team. Continued involvement will be advisable to monitor and manage potential impact on current NEHTA initiatives.

While it may be argued that the barrier to entry is high and that it will require significant resources to develop and sustain conceptual DCMs, to the extent that they can be produced successfully, they will be informative for the development of any and all logical models, including those developed within NEHTA.

There is still an opportunity for national member bodies to modify the output of this work.

Australia should consider future votes on this work carefully. While the work is potentially useful if it becomes resourced and remains aligned with the development of logical models, it may still be better targeting a lesser outcome such as a Technical Report or Technical Specification (as originally sought by Australia, three years ago). Discussions with some other NMBs have indicated that they are considering pushing for demotion of this project.

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<td>WG1</td>
<td>ISO 13972 Quality requirements and methodology for detailed clinical models (DCMs) Parts 1 and 2</td>
<td>The work on ISO 13972 on quality requirements and methodologies in relation to DCMs has been contentious with Australia being among the countries that had voted negatively in a previous ballot (due to a failure of the proponents to maintain an appropriate scope). Given this is a new area driven by isolated activity with little documented research experience to date, Australia has had the view that it may have been more appropriate to publish this work as a Technical Report or Technical Specification rather than an International Standard (IS). The meeting was able to resolve known issues by: • Accepting the essentially non-contentious Part 1 proceeding to CD ballot; • Extracting quality metrics from part 2 and rewriting it for a CD ballot, including reference to a subsequent part dealing with this; • Agreeing to working up a proposal for a new, separate area, at this stage as a part 3 for the material currently addressed in part 2.</td>
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<td>Action: IT-014-09 to arrange discussion and lead preparation of ballot response and comment on the ballot of ISO/CD 13972 Part 1 (expected November) and ISO/CD 13972 Part 2 (expected December) – with a view to ensuring that Australia’s concerns are addressed.</td>
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<tr>
<td>WG1</td>
<td>ISO 13972 Quality requirements and methodology for DCMs Part 3</td>
<td>Work has not commenced on Part 3 and in order to participate, Australia would see value in Part 3 commensurate with the likely resource allocation required to contribute meaningfully to the work.</td>
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<td>Action: IT-014-09 consults with NEHTA and other clinical modelling stakeholders and identifies the content, development process and timeframes likely to be needed in development of Part 3 of ISO 13972 and evaluates whether the level of resourcing required can be found to work allocate on Part 3</td>
<td>NEHTA</td>
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Within the TC 215/WG 1 expert group working on ISO 13972 there is disagreement over obligatory bindings to concept codes. Based on their experiences, the Australian team feel this will lead to non-workable applications.

**Action:** IT-014-09 to investigate implications of obligatory bindings and submit its findings to the ISO 13972 project team.

A diagram reproduced in Part 2 of ISO 13972 Quality requirements and methodology for [DCMs] was originally developed by Heather Grain and Evelyn Hovenga. They have indicated that they are prepared to share this intellectual property with the standards community at no cost but the source and copyright need to be acknowledged.

**Action:** IT-014 to obtain detailed background from the original authors of the relevant diagram in ISO 13972-2 and seek advice from Standards Australia on how the licensing of their intellectual property for use in this standard is best addressed.

8.7 **ISO/TR 17991 GUIDANCE ON STANDARDS FOR ENABLING SAFETY IN HEALTH SOFTWARE**

The NP to undertake this work recently passed ballot. Experts were promised to take part in the work from Australia, Finland, Japan, Kenya, Netherlands, Canada and the UK; however, the relevant Australian expert still needs to be confirmed and nominated through the TC 215 Secretariat.

Disposition of comments has been partially completed. Some queries needing clarification were aired in the meeting and input provided by all those present.

Recent TC 215 work in this area began with the ‘Software as a medical device’ project (Canada), followed up with a symposium at the Rotterdam ISO meeting in October 2010. This triggered the proposal for development of this technical report (which should not be confused with earlier work on risk management of health software in TC 215 or the current activity in IEC/62A/JWG 7 on ISO/IEC 82304-1 Healthcare Software Systems – Part 1: General requirements.

The key purpose of the proposed technical report is to identify “Which standards should be used to enable safety in health software?” and this is reflected in the formal scope: ”Identification of the coherent set of international standards needed for the patient-safe (safer) development, implementation and use of health software”. The following three genres of standards relevant to this scope have been identified: process-centric standards, risk-centric standards and attribute-centric (or property-centric) standards.

The next steps are to describe further the methodology for identifying standards, the criteria for assessment and to look for evidence of use for many of the assessed standards (noting that some relevant material may also not be accessible)

Analysis to this point has shown that there are seven standards with major overlaps in the design/development and component/application section of the current assessment matrix. This requires ideas and input on what that overlap means, its significance and development of a commentary.

There are two major sections left to develop before this document is ready for further general consideration – gaps/overlaps and implementation/use. These sections will be important and key to the use of the technical report

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ISO DTS 29321 & DTR 29322 relating to Application of Clinical Risk Management to the Manufacture/Use of Health Software, which failed at final ballot due to concerns of the medical devices community over the potential for different types of certification to be mandate for clinical device software.
Project lead, Don Newsham, invited Input and ideas from the meeting and sought participation in the development work, indicating that all input would be most welcome.

Relevance to Australia

This will be interesting work for Australia to watch closely and to begin engaging with. Clearly the international trend is towards identification of Software as a Regulated Device and Australia will have to formulate its approach to this new development, with safe software development and use as a priority consideration in eHealth.

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<td>WG1, 3, 4, 8 Standards enabling safety in healthcare software</td>
<td>TR 17991 Guidance on Standards for Enabling Safety in Health Software attempts to answer questions about which standards to follow to enable safety in health software and reduce risks to patients, such as through usability requirements and rigorous testing. The international trend is clearly toward growing regulation of software as a medical device (SAMD) and there is considerable tension between the medical software industry and the medical devices industry over whose standards should prevail. Australia will have to formulate its approach to these new developments, with safe development and use of software becoming an increasingly important consideration in eHealth. This is relevant to all sectors in Australia at a time when many clinical systems are being deployed that introduce risk due to issues related to usability and user acceptance. There is also a need to understand and develop a long term strategy aligning safety in software with other regulatory mechanisms for safety in healthcare (particularly those managed by the TGA). <strong>Action:</strong> IT-014 to monitor and contribute to development of TR 17991 Guidance on Standards for Enabling Safety in Health Software by seeking to involve experts across all health care sectors and in all relevant agencies.</td>
<td>IT-014 DoHA</td>
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8.8 ISO/CD 13940 SYSTEM OF CONCEPTS TO SUPPORT CONTINUITY OF CARE – CONTSYS

The ISO 13940 System of concepts to support continuity of care (Contsys) standard is based on refinement of a well-established European standard and will provide a framework of common concepts for expressing clinical and workflow activities and requirements surrounding the delivery of healthcare.

This work passed ballot to become an ISO work item in April 2011. The underlying European work in this area provides a framework for defining cross-professional, and cross-workflow requirements within the healthcare sector and has undergone extensive review. Much of the modelling involved is now stable and tested in Sweden and England, though not all structures, particularly provider structures, meet Australian needs. Following recommendations from the Australian delegation to the May meeting Dr Graeme Miller, was nominated as an appropriate Australian to be a member of the expert group working on this standard.

This is a joint activity of WG 1, WG 3 and WG 8 in TC 215 and CEN/TC 251 with ISO/TC 215/WG 3 having the lead.
A committee draft (CD) is being prepared for ballot for elevation to a draft international standard (DIS) in 2011/Q4. The focus at this meeting was the receipt of a status report and a walk-through of the project website (webex presentation).

Key points arising from discussion included:

- The standard is aimed at a broad range of users and seeks to establish and formalise a consistent framework of concepts related to the delivery of care in interconnected care environments. It is therefore essential that Contsys inform the SKM activity and that its definitions align with those being maintained in SKMT, notably key definitions such as – health care, continuity of care, information, concept and data.

- Contsys includes and is based on a set of conceptual models but it is noted that these are not conceptual data models, despite their being represented using UML as a formalism.


- There are at least six case studies highlighting how Contsys is being used – encompassing work in the UK, Sweden and Italy among others.

- NHS applied Contsys to telehealth as a test. It was concluded that the telehealth program could have benefited from using the Contsys terms and framework.

- CEN/TC 251/WG 1 is planning to use Contsys for ensuring coherence across all products and alignment with strategies.

- The European epSOS project is also considering whether it can adopt it for use, although this might be problematic given short time frames for development.

There was strong support for JIC to consider Contsys as a JIC project, in order to inform the other SDOs in JIC and to assist coordinating concepts and terms related to continuity of care and electronic health records across standards and across SDOs. JIC is understood to have accepted the suggestion and strengthens the potential for Contsys to be one of the key foundations for eHealth that needs to be developed and built on.

In its own environment, HL7 has developed many use cases and models of clinical concepts such as condition tracking which have value to Australia. These are represented at an abstract level by DAMs in HL7 and elsewhere as DCMs. Australian experts consider that Contsys could provide benefit in driving greater alignment between HL7 DAMs and DCMs as implemented in Australia.

Although use of Contsys has been considered from time to time at the HL7 Patient Care (PC) Work Group, it has not been a priority and there is little interest in alignment. Nevertheless, Contsys is now a JIC project and Australia can more strongly encourage participation in its development and its adoption by other JIC members, including HL7.

**Relevance to Australia**

This work does not currently have a very high profile in Australia, but should be promoted actively for consideration in Australia as it matures. It is difficult to participate because, although the work is a joint with ISO/CEN project with ISO lead under the Vienna Agreement, most of the underlying activity is taking place in Europe. We need to try and ensure that work is not delayed with the next meeting of TC 215 in May 2012 being in Vancouver (some of the Europeans have difficulty getting to meetings outside Europe).

There is potential for this work to inform the NEHTA CI team DCM and specification development.
Current Australian clinical software does not deal well with representing the clinical connections between problems, diagnosis, issues, procedures, and diagnostic tests. In practice, our EHR systems do not tend represent the data in a multi-axial way that clinicians think, and that the practice of medicine requires – we still tend to operate in the same linear way that we have traditionally recorded this information in paper records, which tends to oversimplify the clinical situation. The work of Contsys will support a multi-axial approach to condition/problem management in EHRs, as per the experience in UK and Europe, including development of Problem Oriented Medical Records. This enables advantage in linking and tracking progress of conditions and management for persistence in EHRs and in health information exchange, but will become more of an issue as we increasingly start to operate in a shared health record environment, such as the PCEHR will bring.

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<tr>
<td>WG1, 3 &amp; 8 System of concepts to support continuity of care (Contsys) JIC</td>
<td>Contsys was originally a European (CEN) standard and is potentially one of the more significant pieces of work undertaken by the international standards community and promises to be useful to support interoperability, referral and PCEHR activities. Contsys is an integrative, high level model which covers areas typically developed in isolation - content, terminologies and concepts, interactions, messages and health records – and relates them to underlying care processes. The system of concepts supports continuity of care, bringing together high level ideas of how business and clinical content fits together. HL7 has developed many use cases and models of clinical concepts which are represented at an abstract level by DAMs. HL7’s approaches tends to have been independent of other modelling approaches including DCMs. Australian experts consider that there would be considerable benefit in using Contsys to drive greater alignment between HL7 DAMs and DCMs as implemented in Australia. Now Contsys is a JIC project, Australia can more strongly encourage participation in its development and its adoption by other JIC members, including HL7. <strong>Action:</strong> IT-014 to seek active engagement from NEHTA, the jurisdictions and its working groups within IT-014 to provide active input to the development of Contsys. <strong>Action:</strong> IT-014-06-06 and NEHTA to review Australian implementation guides for Referral and Discharge, related Structured Documents and CDA specifications against Contsys for consistency of concepts and models. <strong>Action:</strong> HL7 WGM delegates to continue encouraging HL7 (and its Patient Care WG) to participate in development of Contsys through the HL7 JIC representation.</td>
<td>IT-014 NEHTA HL7 Delegates Jurisdictions</td>
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8.9 ISO DIS 16527 PHR SYSTEM FUNCTIONAL MODEL

The current HL7 Personal Health System Functional Model (PHR-S FM) DSTU is presently undergoing extensive review and update within HL7 with a view to being balloted as a full HL7/ANSI standard and also as an ISO standard. This involves weekly teleconferences and some face-to-face meetings (mainly at HL7 WGMs). Interested TC 215 experts are invited and welcome to participate in this joint work activity.
The recent NP ballot in TC 215 received 190 comments. These have now been reconciled but some issues remain that need further clarification. The expert group developing this piece of work within HL7 are now ready to apply these reconciled comments back to update the draft document.

There was discussion of some of the issues raised in responses to comments.

This work is also taking into account the parallel activity and changes merging from upgrading the EHR-S FM to Release 2 and it is anticipated that the 1000 or so conformance statements in the PHR-S FM so far will increase in number and become more aligned with the EHR-S FM.

Next steps: It is anticipated that a joint ballot draft will be ready for distribution in February 2012 and will close five months later in July – with ballot reconciliation being planned for the July to September timeframe.

Relevance to Australia

Australia should keep a close watching brief on this work, in reference to its potential impact on the PCEHR development

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<td>WG8</td>
<td>Australia should continue to keep a watching brief on this work, in reference to its potential impact on the shared EHR applications, which may proliferate as conformant repositories linked to the PCEHR. The principal work on developing a standard from the current HL7 DSTU is progressing through the HL7 EHR WG, <strong>Action: IT-014-09 to maintain a watching brief and arrange expert comment when balloted in ISO (mid to late 2012).</strong></td>
<td>IT-014-09</td>
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<td>ISO DIS 16527 PHR system functional model</td>
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8.10 ISO DIS 10781 – EHR SYSTEM FUNCTIONAL MODEL – RELEASE 2

Development of the revised Release 2 of the HL7 EHR Systems Functional Model (EHR-S FM) is now well into thousands of person hours through weekly teleconferences supplemented by additional face-to-face sessions on an ad hoc basis, with input being consolidated from:

- Comments from ISO, CEN and HL7 that were “parked” from the DIS/FDIS ballots of Release 1.1 (R1.1)
- Comments from the R2 NP ballots
- Nine HL7 Functional profiles (FPs) that were developed based on R1.1 and used in systems certification programs
- Ten CCHIT Functional profiles,
- Work on the PHR Systems Functional Model

The net result has been an increase of over 1,000 new criteria in R2.

A verb hierarchy was established and continues to be maintained to ensure consistency, uniformity and rigor to documenting the criteria.

The draft for DIS ballot is in the process of being finalised and is expected to be submitted for processing by the TC 215 secretariat as soon as it is ready.
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| WG8 ISO DIS 16527 PHR system functional model | Australia should continue to keep a watching brief on this work, in reference to its potential impact on the shared HER applications, which may proliferate as conformant repositories linked to the PCEHR. The principal work on developing a standard from the current HL7 DSTU is progressing through the HL7 HER WG. 
*Action: IT-014-09 to maintain a watching brief and arrange expert comment when balloted in ISO (mid to late 2012)* | IT-014-09 |

9. **WG 2 – DATA INTERCHANGE**

| Australian Delegate Attendance | David Rowlands  
Janette Gogler  
David Rowed  
Heather Grain |

9.1 **GENERAL**

Among other things, Working Group 2 "Data Interchange" (WG2) deals with eHealth messaging and communication standards submitted to ISO TC 215 from other organisations such as HL7, IHE and CDISC as well as from the national member bodies.

It is the committee most closely involved with HL7 International's outreach into the international standards community and the forum through which HL7 standards including V2.x, V3 RIM, CDA and the HL7 HDF were progressed to become international standards.

The current WG2 work on genomics, data types and the BRIDG model originated in and closely parallels work within HL7. On the methodology side, WG2 is the vehicle for recognition of IHE processes within the ISO community. Conformance testing and compliance and quality are now seen as part of WG2's scope.

Standards being progressed and maintained by WG2 are among those most essential for support of the Australian eHealth program; however, they are typically available in a more contemporary form from the particular SDO from which they originated.

Michael L Glickman (USA) was the current Convener and Michio Kimura (Japan) is the Vice-Convener.

Under TC 215's internal rules Mike Glickman's maximum 6-year term as convener of WG 2 expired but TC 215 has agreed to his continuing in the role until the present reorganisation activities are concluded.

Work in WG 2 has been somewhat interrupted during the last six months, largely due issues associated with the change in TC 215 Secretariats. However, affected work items were set back on track at this somewhat process-oriented meeting. Four resolutions were commended to the closing Mini-Plenary, which were approved.

The next meeting of WG 2 will be joint with HL7 International and DICOM and is planned for Friday, 20 January 2012 in San Antonio to follow the main HL7 International Working Group meeting being held in that city.
9.2 STANDARDS PUBLISHED AND IN PUBLICATION

ISO 10159 *Health Informatics – Messages and communication - Web Access Reference Manifest* passed unanimous DIS ballot in 2010 and was approved for publication without going to FDIS stage but appears to still be with ISO/CS pending publication, despite publication being announced at the meeting.

9.3 IHE INTEGRATION PROFILES

9.3.1 TR 28380 IHE GLOBAL STANDARDS ADOPTION – PARTS 1 AND 2

This work brings key IHE (Integrating the Healthcare Enterprise) procedures into ISO documents to strengthen approaches for better and more interoperable implementations of the DICOM and HL7 standards and to provide a clearer relationship between IHE initiatives and those of the standards community. The main work to date has focussed on two deliverables:

- **ISO/DTR 28380-1 Health informatics - IHE global standards adoption – Part 1: Process**
- **ISO/DTR 28380-2 Health informatics - IHE global standards adoption Part 2 - Integration and content profiles**

TR 28380-1 passed DTR ballot in 2007; TR 28380-2 passed DTR ballot in 2008; and all comments have been resolved. However, substantial delays in proceeding to publication have been concerned with the formatting of the documents.

The material has already been published by IHE in IHE format. Publication in ISO format involves substantial work for no perceived added value, and accordingly volunteers have been unwilling to undertake this work.

This scenario was predicated on IHE’s status as a “Liaison D” organisation to ISO TC 215, meaning that the liaison is at the WG 2 level, rather than with the TC 215 head committee. TC 215 has now granted IHE full “Liaison A” status, which is at the TC level.

Publications sourced from Liaison A organisations can substantially be published in their own source format, but with ISO’s first (four) introductory sections (Introduction, Scope, Normative references, Terms & Definitions) overlaid. This should make the publication process much easier. The TC 215 Secretariat will liaise with the ISO Central Secretariat to obtain agreement regarding this “cover sheet” publication strategy. A senior staffer from the American National Standards Institute (ANSI) will assist.

Similar issues in relation to problems with the ISO publication formats exist in relation to other liaison organisations including HL7 and CDISC.

Relevance to Australia

IHE profiles are widely gaining acceptance in the eHealth community and often requirements for solutions reference IHE profiles as requirements of software solutions being procured in the marketplace. The PCEHR design indicates that compliance to IHE XDS specifications (amongst others) was potentially required and those working in the radiology and clinical imaging space generally view IHE profiles as the industry norm.

At previous meetings Australia has been strong in expressing is concerns about the delay in publishing these documents, noting that projects for any other types of standards publication would have lapsed several years ago, if publication had taken so long. These have escaped that fate by being technical reports – but the day must still raise questions about the currency of some of the content.
9.3.2 PROPOSED ISO/TR 28380-3 IHE GLOBAL STANDARDS ADOPTION – PART 3: DEPLOYMENT

WG 2 determined that a third and final part of the technical report on IHE is required, to be entitled:

- ISO/TR 28380-3 Health informatics - IHE Global Standards Adoption -Part 3:Deployment

This part will describe how to use the IHE specifications, including how to analyse interoperability requirements in respect of a specific use case; propose a small number of examples to illustrate this methodology; and identify the deployment benefits of a profile based specification of interoperability.

TC 215 endorsed WG2's recommendation to conduct an NP ballot to seek member approval for work on the proposed technical report, Health informatics - Messages and communication - IHE global standards adoption process – Part 3: Deployment. All being well, this ballot is expected to be placed on the ISO/TC 215 balloting portal in December 2011.

The overall concept is a three-part technical report describing the realm of IHE and how to leverage it in standardisation.

Relevance to Australia

As indicated in the previous section, IHE profiles are widely gaining acceptance in the eHealth community and often solution requirements reference IHE profiles to be met by software solutions being procured in the marketplace. This third part to the IHE global standards adoption technical report deserves support as a means of providing practical guidance on how the various IHE techniques can be practically leveraged.

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<th>Topic</th>
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<tr>
<td>WG2 NP: deployment of global standards in collaboration with IHE.</td>
<td>This Work Item progresses some of the Integrating the Healthcare Enterprise (IHE) procedures into ISO standard documents to strengthen the approaches for better and more interoperable implementations of the DICOM and HL7 standards and provide a clearer relationship between IHE initiatives and those of the standards community. Two parts of a Technical Report (TR 28380) are being produced, dealing with: The IHE global standards adoption process (Part 1); and IHE Integration and Content Profiles (Part 2)</td>
<td>IT-014-06 IHE Australia HL7 Australia</td>
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Unfortunately, despite a positive vote in August 2007, the approved drafts have yet to be updated into final ISO form and published but they continue to be available as IHE documents. The positive development at this meeting was that IHE’s relationship with ISO TC 215 has progressed to “Liaison A” status, which means that the documents should be able to be published largely in their source formats.

WG 2 also determined that a third and final part of this technical report is required, describing how to use the IHE specifications. Collectively, the 3 part series will provide a Technical Report describing the realm of IHE and how to leverage it in standardisation.

An NP ballot to start work on IHE global standards adoption process – Part 3: Deployment as a technical report is expected in 2011Q4.

**Action:** IT-014-06 to liaise with IHE Australia and other relevant stakeholders to keep publication pressure on the first 2 parts, and consider the third.
9.4 CLINICAL DOCUMENT REGISTRY FEDERATION (TR 13128)

ISO/TR 13128 Health informatics - Clinical Document Registry Federation, originally proposed as a work item by South Korea defines an extension to the IHE Document Registry in order to allow implementation of a federated registry/access model.

TR 13128 passed DTR ballot in 2010 and all comments were resolved at the last TC 215 meeting in Finland (May 2011), at which the TC agreed that the revised document should proceed to publication.

The DTR was subsequently edited and the requisite documents submitted to the TC 215 Secretariat. Nevertheless, it was not forwarded to the ISO Central Secretariat, probably due to the changeover of TC 215 Secretariat from HIMSS to AHIMA.

The requisite documentation has now been re-sent to the new TC Secretariat, and should proceed to publication as previously intended. No further action was required from TC 215 at this meeting.

Relevance to Australia

The PCEHR design indicates that compliance to IHE XDS specifications (amongst others) was potentially required and those working in the radiology and clinical imaging space generally view IHE profiles as the industry norm. It will be important to track this item to understand any downstream impact on any IHE compliant document repositories, especially those which have the potential (or are) federated.

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<tr>
<td>WG2 ISO TR 13128 Clinical document registry federation</td>
<td>ISO TR 13128 defines an extension to the IHE Document Registry in order to allow a federated registry/access model. TC 215 agreed at its last meeting in May 2011 that the draft should proceed to publication; however, publication was delayed. Matters are now back on track and no further action was required from TC 215 at this meeting. Action: None required from IT-014. Standards Australia to note.</td>
<td>Standards Australia</td>
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9.5 MOBILE HEALTH USING MOBILE/SMART DEVICES

This work item was brought forward by South Korea to address issues around the provision of health applications on mobile/smart devices.

A typical use-case would be as follows. One particular health service may involve several family members with different mobile/smart devices: Smart phone, smart TV, smart eBook, etc. A child has type 1 diabetes that is monitored by a physician. However, the parents are separated and the child is living with mother in A region and father living in B region. On a regular basis, the child, mother and father (sometimes grandparents as well) discuss the child's condition with the physician using their own smart devices.

Beyond simple video conferencing, this requires diverse services/capabilities such as displaying a graph of daily sugar levels and other relevant clinical documents/information, etc.

The NP ballot for TR 17522 Health informatics - Provisions for health applications on mobile/smart devices was circulated following the last TC 215 meeting in Finland (May 2011). The work item passed
ballot and was added to TC 215’s work program with 23 (out of 30) countries responding with a vote – 13 in favour, 2 (Germany and The Netherlands) against and 8 abstaining.

Experts were nominated from Australia (Heather Leslie), Finland (Arto Holopainen, Ilkka Vartiainen), Japan (Natsuki Tanji), Korea (Byoung-Kee Yi), and the United Kingdom (Mike Short, Howard Leicester). Australia noted that little information had been provided and that the proposed standards needs a lot more work.

At this meeting, comments provided during the NP ballot were disposed. Further development of the draft TR will proceed, for consideration at the next WG 2 meeting.

It was noted that there is a relevant IHE work item in the pipeline (XDS for mobiles), and accordingly IHE will provide a liaison to this project. The proposed IHE profile will have similar actors to XDS.b (Cross Enterprise Data Sharing). However, “Mobile Document Source” and “Mobile Document Receiver” will replace the Document Source and Document Consumer actors. Two new transactions will be defined that replace the Provide and Register Document Request and Stored Query transactions. These transactions will be optimized for use using XMLHttpRequest objects. The existing Retrieve Document transaction could be used to retrieve an individual document as it is already friendly to XMLHttpRequest, or a simplified Retrieve Document Set transaction could be created.

This also recognises that a whole new infrastructure is necessary for connection to potentially millions of mobile and smart devices at application level, which was drawn to the attention of HL7 at its September meeting by the head of Canada Health Infoway.

Relevance to Australia

Areas such as remote health monitoring are gaining increased interest in Australia and there are a number of projects/vendors currently pursuing opportunities in this area. As the whole mobile/remote health market is an emerging sector there is likely to be many different approaches taken and therefore a need to standardise in this area may arise.

Australian developers and users have been looking at the need to develop standards for modularisation in the application space, including taking this through Patient Care, SOA and CDS in HL7. There is no one place in Standards Australia to address these functionally decomposed, inter-component needs along the same lines as the existing inter-enterprise and inter-application communication standards. Smart devices will need to address this same need for the next generation of highly fluid applications. DoHA and RACGP have done extensive work in functional groupings in the application space which can be assisted in their advancement by standards like these.

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<tr>
<td>WG2 TR 17522 Provisions for Health Applications on Mobile and Smart Devices.</td>
<td>This work item addresses issues around the provision of Health Applications on Mobile/Smart Devices. Beyond simple video conferencing, this requires diverse services/capabilities such as displaying measurements and other relevant clinical documents and information consistently across a range of devices. It recently passed NP ballot and, at this meeting, comments provided during the NP ballot were disposed. It was noted that there is a relevant IHE work item in the pipeline (XDS for mobiles), and accordingly IHE will provide a liaison to this project.</td>
<td>Standards Australia MSIA HL7 Australia HL7 WG Delegations IHE Australia DoHA and RACGP</td>
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</table>
Australian developers and users have been looking at the need to
develop standards for modularisation in the application space, and
taking this through Patient Care, SOA and CDS in HL7. There is no
one place in Standards Australia to address these functionally
decomposed, inter-component needs.

Action: Set up a task force within the Australian Standards,
industry and user communities to organise this work, articulate
strategy and support this project at ISO through wide distribution
and engagement in these communities. Advance this also through
HL7 International at PC, SOA, CDS and RIMBAA.

9.6 HL7 CLINICAL GENOMICS - PEDIGREE PROJECT

This work item (ISO 13449 Health informatics - Clinical genomics pedigree topic) deals with standard
clinical representation of pedigree (including visualisation) separate to the use of the underlying
information for other Health IT purposes. The work item was accepted in May 2009 with experts
nominated from Brazil, Germany, Japan, UK and USA.

ISO 13449 was unanimously passed by the 14 voters responding to the DIS ballot in April 2011, and all
comments were resolved at the last TC 215 meeting in Finland (May 2011), at which TC 215 agreed
that the revised document should proceed directly to publication (an FDIS ballot not being required
because of the unanimous vote in favour and the final edits being relatively minor).

However, the requisite documentation did not appear to have been forwarded to the ISO Central
Secretariat, and the project leader was unavailable at this meeting, so its status was uncertain. The
WG 2 Convenor undertook to follow up with the TC 215 Secretariat and facilitate this item proceeding
to publication as previously intended. No further action was required from TC 215 at this meeting.

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<tr>
<td>WG2 IS13449 Clinical Genomics - Pedigree Project</td>
<td>This Work Item (IS 13449) deals with pedigree representation (including visualisation) providing standard clinical representation. IS 13449 passed DIS ballot in April 2011, and all comments were resolved at the last TC 215 meeting (Finland, May 2011), at which the TC agreed that the revised document should proceed to publication. However, it appears that the requisite documentation has not yet been forwarded to the ISO Central Secretariat. The WG2 Convenor / TC 215 Secretariat will follow up and facilitate this item proceeding to publication as previously intended.</td>
<td>Standards Australia</td>
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9.7 UPDATE OF HL7 REFERENCE INFORMATION MODEL (RIM)

In 2005, ISO/TC 215 approved ISO/HL7 21731 Health informatics: — HL7 version 3 — Reference
information model - Release 1, which was published by ISO in August 2006.

HL7 has an ongoing maintenance process that produces a new release of the HL7 Reference
Information Model (RIM) annually. Release 4 is scheduled for publication by HL7 International in
November/December 2011.
The current work item being progressed by WG 2 seeks to:

(1) Define a balloting and maintenance project for the RIM that includes participation from ISO/TC 215 in each annual maintenance cycle in order that the joint ISO/HL7 Reference Information Model can be published synchronously with the HL7 release; and

(2) Commence using that process to update ISO 21731 to the current HL7 RIM at the end of calendar year 2011 or 2012, and maintain ISO 21731 in step with the HL7 RIM thereafter. The HL7 RIM is now formally bound to the data types in ISO/FDIS 21090.

The critical issue is that HL7 International has in place an annual process to update the RIM, whereas ISO’s publication processes are slower. ISO has in place a range of more dynamic options, including for the maintenance of databases and the nomination of external organisations as Registration Authorities or Maintenance Agencies. These options have been discussed at WG 2 meetings over the last 12 months, and advice received from the ISO Central Secretariat and others.

After further consideration at this meeting, it was determined that none of these more dynamic options is really suitable for maintenance and timely publication of the RIM. WG 2 agreed that the ISO version will be updated on a two yearly basis, since year to year changes are generally relatively minor. A fast-track process under the ISO-HL7 agreement will be used, whereby if approved as a new work item, the new release can proceed directly to DIS ballot.

More recent versions of the RIM underpin CDA which is the subject of CDA implementation guides developed by NEHTA and proposed as Australian Standards through IT-014-06-06.

TC 215 resolved that an NP ballot on Revision of ISO 27131 would be issued, seeking a concurrent DIS ballot under the fast track process.

Note: Similar issues apply to the work on the BRIDG model discussed in the next section.

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<tr>
<td>WG2</td>
<td>ISO/HL7 21731:2006 Health informatics - HL7 version 3 - Reference information model - Release 1 was published in 2006. HL7 has an ongoing maintenance process that produces a new release of the HL7 Reference Information Model (RIM) annually. Release 4 is scheduled for publication by HL7 International in Nov/Dec 2011. A critical issue is that HL7 International has in place an annual process to update the RIM, whereas ISO’s publication processes are slower.</td>
<td>IT-014 IT-014-06-06 NEHTA</td>
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<tr>
<td>HL7 RIM: Revision of ISO 27131</td>
<td>After consideration of options, it was determined that the ISO version will be updated on a two yearly basis, since year to year changes are now generally relatively minor. A fast-track process under the ISO-HL7 Agreement will be used, whereby if approved as a new work item, the new release can proceed directly to DIS ballot. <strong>Action:</strong> Support revision of the HL7 V3 RIM as an ISO standard together with a process for practical, periodic updates to track the releases at HL7.</td>
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9.8 BRIDG MODEL FOR PROTOCOL-DRIVEN BIOMEDICAL RESEARCH

BRIDG formally known as the Biomedical Research Integrated Domain Group is a collaborative effort to produce a shared view of both the dynamic and static semantics of protocol-driven research and its
associated regulatory artefacts. Such artefacts include the data, organisation, resources, rules, and processes involved in the formal assessment of the utility, impact, or other pharmacological, physiological, or psychological effects of a drug, procedure, process, subject characteristic, biologic, cosmetic, food or device on a human, animal, or other subject or substance plus all associated regulatory artefacts required for or derived from this effort, including data specifically associated with post-marketing adverse event reporting.

The BRIDG Domain Analysis Model (DAM) has been developed through over 5 years of work and is intended to streamline information flows from development of clinical protocols through analysis and reporting within organisations and will facilitate data sharing across partnering organisations, including healthcare and clinical research entities. BRIDG is an important initial step toward achieving integration between the worlds of healthcare and medical research.

Building a bridge between these two communities is the foundation for faster development of therapies, improved healthcare and patient safety globally. The time between the availability of medical research results and their use to inform healthcare decisions must be shortened in order to detect patient safety issues and important research findings in a more timely manner. In addition, the quality of care can be improved through better processes and research findings.

This work item was balloted by CDISC and became an official CDISC standard in May 2009.

This TC 215 work item relates to the joint development and adoption of BRIDG as ISO 14199 Health Informatics: The BRIDG domain analysis model for protocol-driven biomedical research as an approved joint project on the JIC work program being led by CDISC, with simultaneous approval taking place in ISO/TC 215 and HL7. Active participants have predominantly been US-based: CDISC, NCI, FDA and HL7.

In August 2010, BRIDG 3.0.2 was released and is being used as the basis for the proposed publication of the joint version by CDISC, ISO and HL7.

This document was balloted as the ISO Committee Draft ("CD") and as an HL7 standard in May 2010. V3.0.2 also addresses most of the ISO and HL7 International ballot comments. Key implementations in the US FDA and NCI have further stabilised the specification.

To progress to the next stage, the draft publication has gone to the ISO Central Secretariat for circulation with a DIS ballot. However, there are some formatting issues, and CDISC is working with the Central Secretariat to resolve these.

BRIDG faces similar issues to those of the HL7 RIM as discussed in the previous section. The CDISC version of the document is updated annually, and arrangements for keeping the ISO versions in sync remain a challenge. CDISC will investigate using the same approach as agreed for the HL7 RIM.

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<tr>
<td>WG2 ISO 14199 BRIDG Domain Analysis Model for protocol-driven biomedical</td>
<td>BRIDG is a collaborative effort to produce a shared view of the dynamic and static semantics of protocol-driven research and its associated regulatory artefacts. It is intended to streamline information flows from development of clinical protocols through analysis and reporting within organisations and will facilitate data sharing across partnering organisations, including healthcare and clinical research entities. BRIDG is an important step toward achieving integration between the worlds of healthcare delivery and medical research.</td>
<td>Standards Australia, NHMRC, HL7 International Delegation</td>
</tr>
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</table>
A JIC project sponsored by ISO, HL7, and CDISC is taking the BRIDG model, which was originally developed by CDISC and HL7, through to an international standard. It is potentially important for internationally communicable cooperative research which involves Australia.

BRIDG first became an official CDISC standard in May 2009. In August 2010, BRIDG 3.0.2 was released and this version is being used by CDISC, ISO and HL7 as the basis for the proposed joint version.

The draft publication went to ISO Central Secretariat for circulation with a DIS ballot but there have been formatting issues, and CDISC is working with the Central Secretariat to resolve them.

There are also issues synchronising maintenance of the ISO publication with updates to the underlying BRIDG model. A fast track process has been agreed for updating the model which will involve a hybrid arrangement with CDISC providing material for 2 yearly DIS ballots.

**Action:** Australian delegations to TC 215 to support the fast-track approach at ISO, identify and engage the Australian research communities to ensure this meets their requirements. Ensure the process at HL7, and from there at CDISC, is conducive to ISO process needs.

### 9.9 CLINICAL TRIALS REGISTRATION & REPORTING (CTR&R)

The scope of the proposed standard *Health informatics – Clinical Trials – Registration and Reporting (CTR&R)* is to create a data exchange standard comprising a domain analysis model or "DAM" and data interchange specification to meet the current global requirements for clinical trial registration and clinical trial results reporting.

This work item is intended to support the global data exchange requirements brought about by the increasing number of global, national, and regional as well as organisational clinical trial registries and trial results databases. It will provide a mechanism to transport the protocol-related descriptive information needed to register a clinical trial along with the capability to exchange information summarising trial result outcomes. The project is intended to address the exchange of clinical trial-level summary data and will not be used to transport individual patient-related data.

It is proposed that it be produced as a 2-part standard intended to meet global requirements for clinical trials registration (Part 1) as well as reporting of trial status and summary results (Part 2). The current focus has been almost exclusively on Part 1 and is being led by CDISC and the Regulated Clinical Research Information Management (RCRIM) WG within HL7 International.

The document that is being proposed as a draft for Part 1 of this standard has been through numerous HL7 and CDISC ballots. Accordingly, a fast track process is being sought.

It was resolved at the last TC 215 meeting in Finland (May 2011) that the ISO/TC 215 Secretariat should arrange with ISO/CS to circulate the NP ballot to establish this new work item targeting an International Standard. Unfortunately, this did not happen. It will now be pursued.
WG2 Clinical Trial Registration and Reporting (CTR&R)

The primary purpose of CTR&R standard is to provide seamless data exchange between global pharmaceutical sponsors and clinical trial registration authorities such as US (ClinicalTrials.gov), European Medicines Agency (EMA) (EudraCT) and WHO (Clinical Trial Registry).

It is proposed to be a 2-part standard with Part 1 intended to meet global requirements for clinical trials registration with Part 2 for reporting of trial status and summary results.

It was resolved at the last TC 215 meeting in May 2011 that the ISO/TC 215 Secretariat should circulate an NP ballot for approval as a new work item targeting an International Standard using the fast-track process. Unfortunately, this did not happen but will now be pursued.

Action: On receipt of the ballot documentation, IT-014 to seek input from the local clinical trials community on Australian perspectives and potential participation in the work.

Standards Australia NEHTA TGA

9.10 QUALITY CRITERIA FOR SERVICES AND SYSTEMS IN TELEHEALTH

Work on TS 13131 Quality Criteria for services and systems for telehealth seeks to define criteria for a process or set of processes aiming at improving or enabling health and health care using information technology and telecommunications to reduce the effect of distance in space and/or time between the actors.

The new work item proposal (NP ballot) for ISO/TS 13131 was approved in 2009 based on previous Dutch work, which focussed on identifying acceptable telemedicine practices (partly for reimbursement purposes).

The scope and the key concepts to be included in the definition of "telehealth" were the biggest issues - Australian and Brazil had actively participated in these discussions. As a result, the title was changed from "telemedicine" to "telehealth", with telemedicine being seen as a subset of telehealth. A change in project leadership caused delay.

By the last TC 215 meeting in Finland (May 2011), a third draft had been produced, and it was resolved that the DTS ballot be placed on the ISO/TC web site by July 2011.

It was ascertained that the requisite documentation had gone to the ISO Central Secretariat but the document has never been balloted. This will be followed up by the new TC 215 Secretariat.
This work seeks to define criteria for a process or set of processes aiming at improving or enabling health and health care using information technology and telecommunications to reduce the effect of distance in space and/or time between the actors.

By the last TC 215 meeting (Finland, May 2011), a third draft had been produced, and it was resolved that the DTS ballot should be placed on the ISO/TC web site by July 2011. Despite the requisite documentation having gone to the ISO Central Secretariat the document has never been balloted. This will be followed up.

*Action: IT-014-012 to advise on the NP ballot, when posted. If there are no serious comments then hopefully there can be resolution of issues prior to the next ISO meeting in May 2012.*

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**9.11 WEB ACCESS TO DICOM IMAGING OBJECTS (WADO)**

At its October 2009 meeting, WG 2 determined that the original *ISO 17432:2002 Web access to DICOM persistent objects (WADO)* standard should be expanded with new web services enhancements and published as a revised version.

The additional content is now part of DICOM standard, in the form of a DICOM supplement (Supplement 148: Web Access to DICOM Persistent Objects by Means of Web Services Extension of the Retrieve Service (WADO Web Service)). In developing the supplement, a few changes were made to the original WADO to make it work with web services.

There was again discussion about the most appropriate form of publication and WG 2 determined that the “cover sheet” approach available to ISO Liaison A organisations (which includes DICOM) should be used. This involves overlaying the four ISO introductory sections (Introduction, Scope, Normative references, Terms & Definitions) on the source document rather than completely reformatting it. This makes the publication process much easier.

Accordingly, WG 2 proposed and TC 215 resolved that the joint TC 215/WG 2 and DICOM project team add the first four ISO document clauses to the WADO-WS document and authorize the ISO Central Secretariat to issue it as a DIS ballot. A completed document will be provided to the TC Secretariat no later than 29 February 2012 to be placed on the ISO/TC 215 balloting portal no later than 11 March 2012. This allows for a joint meeting of WG2 and DICOM to consider and refine the draft in January 2012 (at the HL7 International Working Group Meeting in San Antonio).

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<tr>
<td><strong>WG2 Web Access to DICOM persistent Objects by means of Web Services ISO 12974 Supplement 148 - WADO</strong></td>
<td>Web access to DICOM imaging objects (&quot;WADO&quot;). This work proposes that the original ISO 17432:2002 Web access to DICOM persistent objects (WADO) standard should be expanded with new web services enhancements. This now forms part of the DICOM standard, in the form of a supplement (Supplement 148: Web Access to DICOM Persistent Objects by Means of Web Services Extension of the Retrieve Service (WADO Web Service)). A joint TC 215/DICOM project team is to make minor changes in order to finalise the WADO-WS document using the “cover sheet” approach for publishing existing standards from ISO Liaison A organisations. A DIS ballot is expected to issue around March 2012 (following a joint meeting of WG2 at the January 2012 HL7 WGM in San Antonio). Web access to imaging takes place in the Australian health community with clinicians accessing material in private imaging centres through proprietary products which require deployment on client systems. Future directions in Australia, backed by work at NEHTA indicate a move towards services-based solutions for clinical data sharing. Action: IT-014-06 to track progress at the review next WG2 meeting and prepare ballot response and comments with input from NEHTA and other experts.</td>
<td>IT-014-06 NEHTA</td>
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9.12 POTENTIAL WG 2 PROJECTS

The following two suggestions for potential projects within WG 2’s current domain were presented for information and discussion.

9.12.1 CDISC THERAPEUTIC AREA DATA STANDARDS

Much clinical research is done on an international scale by multinational companies; they often enforce their own methods and models for data collection, meaning compliance with multiple standards for healthcare organisations involved in such research.

During the JIC Open Forum, Bron Kisler of CDISC presented on their progress toward realising a vision of informing patient care and safety through higher quality medical research including greater use of standards for aggregate data analysis.

This includes seeking to achieve significant progress in the use of core CDISC standards to facilitate scientifically sound data aggregation and support secondary uses of research data for the purposes of scientific investigation and comparative effectiveness studies.

In particular, he suggested that a range of CDISC Therapeutic Area Data Standards may be of interest to TC 215 in the future. These standards describe data elements used for research into conditions/therapeutic areas such as Tuberculosis; Acute Coronary Syndrome; Polycystic Kidney Disease; Cardio-vascular Disease; Alzheimer’s; Parkinson’s Disease; Pain & Analgesics; Oncology; Other Neurological Disorders; Diabetes; Hepatitis C; Paediatrics; Vaccine Safety; and Schizophrenia.

The CDISC vision of widely adopted international standards in this area could improve the quality of research data and the ability to re-use and compare research conducted over time as well as to improve our national data collections. It could also lead to significant cost savings in research.
The standards are currently under varying stages of development, and CDISC is working with relevant peak bodies and research agencies. The US FDA is keen to promote these as data standards in order to enhance their reporting and analysis processes. CDISC is building its own domain models, and using a controlled terminology hosted by NCI in the US.

Relevance to Australia

Use (and re-use) of trial data in clinical research is a long standing issue in Australia where there is no formal requirement for nationally funded research to use and inform national data collection and metadata. We have strong capability in the AIHW national metadata repository but NHMRC grant processes do not require researchers to use it or contribute to it.

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<th>Topic</th>
<th>Issue / Action / Recommendations for Australia</th>
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<tr>
<td>JIC CDISC Use of standardised data in clinical research WG2</td>
<td>Much clinical research is done on an international scale by multinational companies and they often enforce their own methods and models for data collection, meaning compliance with multiple standards for healthcare organisations involved in such research. During the JIC Open Forum, Bron Kisler of CDISC presented on their progress toward realising a vision of informing patient care and safety through higher quality medical research including greater use of standards for aggregate data analysis. This includes seeking to achieve significant progress in the use of core condition-specific CDISC standards to facilitate scientifically sound data aggregation and support secondary uses of research data for scientific investigation and comparative effectiveness studies. The CDISC vision of widely adopted international standards in this area could improve the quality of research data and the ability to re-use and compare research conducted over time as well as to improve our national data collections. It could also lead to significant cost savings in research. Use (and re-use) of trial data in clinical research is a long standing issue in Australia where there is no requirement for nationally funded research to use and inform national data collections and metadata. <strong>Action:</strong> Engage with NHMRC to improve the relationship of nationally funded research to national data collections and metadata specifications. <strong>Action:</strong> IT-014 to consider how to leverage the CDISC work in Australia.</td>
<td>DOHA NHMRC IT-014</td>
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9.12.2 IHE PEER-TO-PEER SHARING OF HEALTH INFORMATION

IHE has written two profiles for cross community interoperability: XCPD - Cross-Community patient discovery (for identifier systems querying each other); and XCA - Cross-Community Access (for querying and retrieving patient data). The use cases concern information sharing between affinity domains such as Health Information Exchanges (HIEs), regions or countries. They use the concept that sets of profiles working together provide the building blocks for interoperability.

These specifications are being used by the European epSOS project; between Kaiser Permanente and the Veterans’ Health Administration; and between some US HIEs. Other HIEs in the US are understood to be planning to use them.
There will be further discussion of this item at the next WG2 meeting, after existing IHE work program items are progressed.

However, consideration of this item led to a more strategic discussion on the nature of IHE, which has traditionally argued that it is not a standards development organisation (SDO) but, rather, profiles existing standards and therefore does not compete directly with SDOs. The view was expressed that IHE has in fact become an SDO that specialises exclusively in implementation guides, as opposed to base standards and other standards products – noting the various definitions of a standard. For example, Standards Australia’s definition is:

“Standards are published documents setting out specifications and procedures designed to ensure products, services and systems are safe, reliable and consistently perform the way they were intended to. They establish a common language which defines quality and safety criteria.

Standards can be guidance documents including:

- Australian Standards®;
- International Standards and Joint Standards;
- Codes;
- Specifications;
- Handbooks; and
- Guidelines.”

This is an important issue because IHE is understood to be keen to join the JIC. Some in the Australian delegation considered it important that IT-014 (in consultation with Standards Australia) have a position on whether, to all intents and purposes, IHE should be regarded as a standards development organisation or not.

10. Wg 3 – semantic content

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<tr>
<th>Australian Delegate Attendance</th>
<th>Heather Grain (WG 3 Convenor)</th>
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<tr>
<td>Others attended joint sessions with WGs 1 and 8</td>
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10.1 Attendance - Impact of Recent IHTSDO Meeting

This meeting was missing a number of key players due to IHTSDO meeting in Sydney the week prior to the meeting, and the late notice provided by the new secretariat confirming the dates of this meeting. This reduced attendance is not likely to occur on future occasions. It was announced that the TC Secretariat will be developing a meeting schedule much further into the future, over a 5 year period which should make it easier to include at least some meetings jointly with other SDO activities and for Australia to plan more effectively in advance.

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10.2 RESTRUCTURE - LIKELY FUTURE ROLE OF WG 3

It appears likely when the restructure of TC 215 is completed, Working Group 3 will continue to have a role that encompasses:

- underpinning standards for terminologies (excluding specific content – which is managed by IHTSDO and other providers of clinical terminologies and classifications) and
- aspects of ‘semantics’, e.g. decision support, metrics, user interfaces

10.3 DOCUMENTS IN BALLOT

The following work items were not actively discussed as they were out to ballot (or for the other reasons stated):

- **ISO/DIS 13120 – Health Informatics – A syntax to represent the content of classification systems in healthcare** (ballot closing date 21 September 2011 – under VA with ISO lead)

  The original standard on which this work item is based has been used in Europe for some time, to provide semantically consistent structure for representation of concepts coded using ICD and similar systems. This work was scheduled to be discussed in the first teleconference of WG 3 planned for November.

- **ISO/NP TR 12975 Principles and guidelines for the maintenance of terminological systems** (dependent upon *Principles and guidelines for the measurement of conformance in the implementation of terminological systems*).

  The new project (NP) ballot for this work item opened in July and closed on 10 November 2011. There was little discussion as the item was out to ballot. This work was also scheduled to be discussed in the first teleconference of WG 3 planned for November.

- **(prEN) ISO/DIS 1828: Health informatics – Categorial structure for terminological systems of surgical procedures** (currently out for FDIS ballot).

- **ISO/DTR 12300 Health informatics – Principles of mapping between terminological systems** (issued for DTR ballot. IHTSDO liaison to be asked to provide comments)

- **ISO/CD 18104 Health informatics – Categorial structures for representation of nursing diagnoses and nursing actions in terminological systems**

  The Working Group agreed with a proposal from the work item leader, Anne Casey, that the CD ballot date be deferred until after the ISO/TC 215 plenary meetings in Spring 2012 to allow further time for resolution of comments arising from the recent ballot.
• ISO/DTR 16278 Health informatics – Categorial structure of terminological systems for human anatomy (issued for DTR ballot).

10.4 ISO/DIS 13119 CLINICAL KNOWLEDGE RESOURCES – METADATA

The proposed international standard ISO/DIS 13119 – Health informatics – Clinical knowledge resources – Metadata will define the metadata required to describe clinical literature. It extends and more clearly defines this data to support improved clinical knowledge. It includes definitions for knowledge held or published in databases which support clinical decision-making.

The work item passed DIS ballot in September and comment disposition was undertaken at the meeting. Critical decisions included:

- The need to recognise that not all concepts should be described using MESH, and that some knowledge is better described using ICD or SNOMED CT concepts.
- Though its content was generally considered accurate the document needs to use simpler, clearer text in order to meet the broad audience needs.
- Conformance requirements were considered and deemed appropriate for inclusion.
- The document is to use the descriptors from ISO 11179 – metadata registry specification rather than create new descriptors.

All definitions are to be added to the Standards Knowledge Management Tool (SKMT). Heather Grain will assist with this process where required and assist with harmonisation proposals where required.

10.5 ISO/NP TR 12310 - PRINCIPLES AND GUIDELINES FOR THE MEASUREMENT OF CONFORMANCE IN THE IMPLEMENTATION OF TERMINOLOGICAL SYSTEMS

The proposed technical report ISO/TR 12310 Principles and guidelines for the measurement of conformance in the implementation of terminological systems will provide guidance on the methods, risks and approaches to measurement of conformance in terminological systems.

Progression of this work item is awaiting comments from IHTSDO, which are expected by the end of November after which the item will be followed up in the monthly WG 3 teleconference. A separate proposal ISO/NP 12975 Health informatics – Principles and guidelines for the maintenance of terminological systems is dependent upon this work, and will not begin work until it is further advanced.

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<tr>
<td>Conformance of terminological systems - Australian comments</td>
<td>Though some Australian comments have been received on ISO/TR 12310 Principles and guidelines for the measurement of conformance in the implementation of terminological systems this work should be reviewed by the NEHTA CCA group to ensure our requirements are appropriately reflected. <strong>Action: Obtain and submit NEHTA comments. All comments are required to reach the secretary by the end of November.</strong></td>
<td>NEHTA</td>
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10.6 ISO/DTR 13054 STANDARDS KNOWLEDGE MANAGEMENT (SKM)

This technical report has just been balloted and accepted for publication with 15 member bodies in favour, one voting against and 14 abstaining or not voting. Two member bodies submitted comments.

This technical report identifies the content and processes required for the Standards Knowledge Management Tool (SKMT) glossary and harmonisation process for the shared health informatics standards glossary. (www.skmtglossary.org). This open tool currently contains details from TC 215, CEN TC 251, HL7, CDISC, WHO, Canada Health Infoway, Standards Netherlands, Standards Brazil and Standards Finland. Standards Australia has agreed to contribute but work is required to build skills, processes and load appropriate data.

This work is led by Australia (Heather Grain) and supports Australia’s inclusion of terms and definitions from our own documents. The comments will be aggregated and used to update the document.

The primary purposes of the processes set out in this document (including the maintenance of a health informatics standards registry and glossary using SKMT) are to:

- Provide a single point of access to standards from multiple SDOs operating in the health informatics space — acting as a bridge between the standards developers and the end-user;
- Facilitate practical usage so that end users can find appropriate standards for the task at hand based on searching for material using a web-based portal;
- Provide TC 215 with a ‘stake in the ground’ for better knowledge management, to ensure accurate, accessible knowledge about available standards;
- Provide information that allows better management of specific and standardised structured information in standards documents e.g. use of specific sub-headings.

The standards contained in the registry (see www.hiwiki.org/spider for browsing) encompass:

- 2x organisation/people standards;
- 3x process Standards;
- 34x Information standards; and
- 15x Technology standards

In practical terms, the information from the standards registry has been applied in development of health informatics education courses; to assist in identifying standards relevant to the development of TR14639 (Capacity-based eHealth roadmap); and in a PCEHR standards review in Australia.

Ongoing work is required to include more standards in the registry and further enhancements to the underlying system are planned to come over time, to include:

- Updates to the metadata to provide additional information without the need for document update/re-versioning
- Use of additional optional fields e.g. re Links/implementation considerations/projects using/lessons learned

This item was also specifically discussed at the:

- Operations and Harmonisation Meeting, where it was determined that no ISO/TC 215 document will be released for ballot unless document has been entered into the SKMT and its defined terms have been entered into the Glossary and, where appropriate, harmonisation proposals for terms included have been prepared.
• Joint Initiative Council, where it was agreed that a SKMT and Glossary Steering Committee will be established to govern the harmonisation process and provide liaison into each of the SDOs. Draft terms of reference for this group have been developed by Heather Grain and will be further considered by the JIC.

• Cross-SDO meeting, where processes for harmonisation were discussed and processes for further training and governance (gatekeeper processes) were also considered.

Use and development of the health informatics SKM capabilities is now a recurring agenda item at the JIC and Cross-SDO forums to ensure that it bridges all SDOs and meets identified needs of the user communities with more SDOs agreeing to participate.

Next steps: Comments from the recent ballot are planned to be addressed to a reasonable level by mid-December after which the technical report will be sent to ISO for publication, in accordance with a resolution of TC 215.

Relevance to Australia

Having Australian expert involvement will mean that it is likely to stay on the Standards Australia agenda. However now that the SKMT tool is becoming increasingly useful as standards are entered and categorised, and the practical means to navigate the national standards environment becomes more polished, we should be exploring how this resource might be publicised to the Australian stakeholders and vendors, to promote use and awareness.

IT-014 have agreed to contribute to this activity, as have other countries; however resources have yet to be made available for this task, though it is understood that funds have been established through National Health Information Standards and Statistics Committee (NHISSC)/ Australian Health Ministers’ Advisory Council (AHMAC).

The development of an Australian portal to this tool might be worth consideration, allowing easy access to Australian Standards in the first instance, plus the ability to explore deeper to international standards. This type of national portal would potentially complement the project based approach being used in TR 14639 – effectively providing different views/slices through the standards environment that are helpful to end-users.

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<tr>
<td>WG3 DTR 13054, Standards Knowledge Management</td>
<td>DTR 13054 is about to be sent for publication as soon as comments from the recent ballot are incorporated by the relevant experts. IT-014 have agreed to contribute to the SKMT activity, as have other countries; however resources have yet to be made available for this task, though it is understood that funds have been established through NHISSC. NEHTA should be included in this process to allow them to determine whether to load their data into the tool to support a coordinated approach. Action: IT-014 to consult with NEHTA to determine Australian procedures for inclusion of terms and definitions, and publications and plan process for appropriate education of the standards community and load existing data. Action: Standards Australia and NEHTA to explore how this resource might be publicised to the Australian stakeholders and vendors, to promote use and awareness. Action: IT-014-02, Standards Australia and NEHTA to consider development of an Australian standard-specific portal.</td>
<td>IT-014 NEHTA IT-014-02</td>
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10.7 ISO/TS 14668 CLINICAL DECISION SUPPORT AND ALERTS

There is a joint activity between WG 1, WG 8 and WG 3 to produce authoritative consolidated specifications in the area of clinical decision support and clinical alerts, initially targeting the following three technical specifications:

- **ISO/TS 14668-1 … Clinical decision support – Part 1: System foundations**
- **ISO/TS 14668-2 … Clinical decision support – Part 2: Technical foundations**
- **ISO/TS 14668-3 … Clinical decision support – Part 3: Alert system requirements**

The work is based on adapting and extending an Australian handbook\(^5\) to produce the international technical specification with each of the three parts targeted at different audiences.

Heather Grain provided a status update to a joint session of WGs 1, 3 and 8, which was followed by a brief discussion on the definition of ‘alert’ in context of decision support. Heather undertook to refine the ideas. There was also significant discussion re controversial comments.

The comments from the initial ballot were discussed and resolved and the full comment disposition and an updated document of Part 1 (Foundation) will be circulated to the experts before January and of the Part 2 (Technical) an Part 3 (Alert) sections by March 2012. These documents will be shared with the HL7 community as their work is specific to messaging while these items cover the principles and process requirements of these systems.

**Relevance to Australia**

Australia has led this work, and should continue to be actively involved in shaping its evolution.

This work should significantly inform the NEHTA CI team in the area of DCM development.

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<tr>
<td><strong>WG3 Decision Support and Alerts</strong></td>
<td>Work on developing ISO/TS 14668 Guidelines for the principles and desirable features of clinical decision support systems is based on earlier Australian IT-014 work and is in three parts: 1. System foundations, 2. Technical foundations, and 3. Alert system requirements</td>
<td>IT-014, NEHTA HL7 Delegates attending CDS</td>
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| **TS 14668 Parts 1 to 3** | This work potentially has a direct relationship to PCEHR and other NEHTA activities. As Australia is leading work on all three components, which are also potentially relevant to NEHTA activities, active NEHTA engagement should be sought both to inform NEHTA activities of this work and to gain input from them. A need for greater clarification over definitions, relationships to work in HL7 and potential further activities in standards for clinical decision support was also raised by some of the Australian delegates  
  
  **Action**: Seek active engagement of NEHTA in this work and ensure clinical, administrative, and technical input to the work.  
  **Action**: Australian delegates to HL7 WGM to work with HL7 CDS WG to arrive at common definitions for CDS concepts and to include them in the SKMT. |

\(^5\) **HB 307-2007 Guide on the principles and desirable features of clinical decision support systems**  

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**10.8 ISO/NP 17583 TERMINOLOGY CONSTRAINTS FOR CODED DATA ELEMENTS**

It was resolved at the last TC 215 meeting in Finland (May 2011) that an NP ballot would be circulated seeking approval for work on a new ISO standard: *ISO 17583 Health informatics – Terminology constraints for coded data elements expressed in ISO harmonized data types used in healthcare information interchange.*

This standard will address how to define and express terminology constraints applicable to coded data elements used in standards and standardized eHealth information models and will describe how to apply terminology to particular data elements, for example in information models, data dictionaries, etc. It will enable people to formally demonstrate the way in which they have applied constraints is valid in terms of the source standards.

This proposal passed ballot with experts being nominated from Japan (Michio Kimura), The Netherlands, UK (Ian Townend) and Australia (Vince McCauley, Heather Leslie, Stephen Chu). Comments included that IHTSDO be included as liaison, and this was agreed. It was proposed that a document be circulated to the expert panel for comment within a month of the Chicago meeting.

The approach is focussed on HL7 information models and is designed for use with the new ISO 21090 harmonised datatypes and CTS2. An earlier draft (the HL7 Core Principles document) had already been balloted in HL7, and the ISO product will be a subset of the HL7 work and subject to joint copyright. The previous work had extensive review in HL7 and draws on substantial practice in Canada Health Infoway.

When static information models and datatypes specifications are designed in the HL7 standards, coded elements must be associated with a specification identifying what type of vocabulary is allowed to be used in the coded expressions for those elements. This is not straightforward. For example, the flexibility built into both HL7 and SNOMED CT means that there is normally more than one way to perform the binding. Yet the ways in which these bindings are undertaken must be clear and understood in order to assure interoperability across a range of applications.

This is highly technical, and needs to be driven by what works in information systems dealing with complex domains.

Comments were discussed and resolved during the meeting, with many reflecting a lack of understanding of the previous HL7 Core Principles work. Heather Grain suggested that the issues raised be made clearer in the document to reduce confusion. Some of the comments indicated that the respondent was considering only SNOMED CT, while the work is far broader than just SNOMED CT.

Great Britain is offering to provide details from the NHS implementation experience to this work. It is excellent that this is now occurring, but disappointing that they had not engaged in the years of work at HL7 as there is now the potential for rework to be required.
Relevance to Australia

This work item is highly relevant to Australian requirement and the NEHTA community as well as IT-014-02 and IT-014-06 and all should be actively reviewing and participating in discussions.

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<tr>
<td>WG3 Expressing terminology constraints on coded data elements (with WG2)</td>
<td>The proposed new standard, ISO 17583 Health informatics – Terminology constraints for coded data elements expressed in ISO harmonized data types used in healthcare information interchange, is based on previous HL7 work on “terminology binding” coming into ISO. It describes how to apply terminology to particular data elements, for example in information models, data dictionaries, etc. and will enable people to formally demonstrate that the way they have constrained is valid in terms of the source standards. The draft specifications have had extensive review in HL7, and draw from substantial practice in Canada Health Infoway. This work item is highly relevant to Australian requirements and the NEHTA community as well as IT-014-06 and IT-014-02 and all should be actively reviewing and participating in discussions. The item recently passed NP ballot as a new work item with experts being nominated, including from Australia. It was noted that discussion is required on comments from UK and Australia, and this will be sought by the project leaders. Australia proposed that IHTSDO be included as liaison, and this was agreed.</td>
<td>IT-014-02 IT-014-06 IT-014-09 Collaborating with: NEHTA HL7 Australia IHE Australia</td>
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Action: IT-014-02, IT-014-06 and IT-014-09 to track this work item and collaborate with NEHTA, HL7 Australia and other key stakeholders to inform Australia’s position.

10.9 HEALTH INFORMATICS – OBJECT IDENTIFIERS (OIDs)

This work is a joint activity of TC 215, HL7 and other relevant technical committees (including ITU-T SG 17) and seeks to provide a consistent model for OID registries and guidance on standardised approaches to maintenance of object identifiers and their metadata across OID registries to support improved interoperability. It comprises two proposed standards:

- ISO 13581 Guidance for maintenance of object identifiers
- ISO 13582 Communication model and XML interface specification for OID registries

The draft documents need to be circulated at committee level for wider input before release to DIS ballot. Australian review of the draft documents will be required. A document draft is in preparation and will be provided to the expert community before Christmas.

Relevance to Australia

OID’s are been widely used in the Australian eHealth environment to uniquely identify objects (primarily data elements and value domains) used in eHealth standards and specifications. For example all objects published by NCTIS are assigned an OID
10.10 ISO/TS 17117-1 TERMINOLOGICAL RESOURCES – PART 1: CHARACTERISTICS

This work is a review of the existing technical specification ISO/TS 17117-1 Terminological resources – Part 1: characteristics, which will be significantly changed given the advances in this area over the last five years. The new work will clarify and identify the pieces of the terminology and classification puzzle. Japan has taken leadership and at this meeting presented proposed classes and concepts for inclusion. This work will now include additional components from the CEN standard EN 12264 categorial structures of systems of concepts.

When this work item to upgrade the previous specification passed ballot as a new project in May this year, initial ballot comments were supportive. It is expected that a draft will be available prior to the next meeting for detailed discussion at that time or via prior teleconference.

This item did not progress at the meeting, due to the inability of its leader to attend the meeting, largely due to the short notice offered, and currently difficulties in Japan.

10.11 CATEGORIAL STRUCTURES FOR REPRESENTATION OF HERBAL MEDICAMENTS

This work involves production of two proposed standards:

- **Health informatics – Categorial structures for representation of herbal medicaments – Part 1: Single natural material**
- **Health informatics – Categorial structures for representation of herbal medicaments – Part 2: Formula of single natural materials**

Part 1 focuses on the categorial structure for herbal medicaments and it is currently suggested that its structure would include:

- Origin (part/whole of source materials) – e.g. where it was grown, the territory, time of harvest
- Processing – how the original item is processed, e.g. dried in the sun, dried in the shade
- Effects on health issues – the impact upon the body of the medicament. This area was acknowledged to be poorly defined and requiring additional work.
- Part Used – root, leaf, stem, bark
- Scientific name.
The structure for 'Formula' in Part 2 will include consideration of:

- Amount of individual single natural material in a formula – dosage, measure
- Effects on health issues of the dosage
- Though western medicine is not the focus of this work, there may be utility to western medicine.

These two new work items are to be progressed together and are to be coordinated with IHTSDO, and WHO. The intent is to define the structures needed to represent both the single elements, and the required elements to represent formulas of these elements. It is intended that this model will indicate where herbal medicaments meet existing SNOMED CT structures.

The meeting accepted these items to go forward for NP ballot as new projects.

Document drafts are in preparation and should be provided to the expert community before Christmas.

Relevance to Australia

Australia has a strong academic and practice based traditional medicine culture. This work item is relevant to that community and also the mainstream medical community especially in areas such as decision support and research where a standard way for representing these items will be essentially to integration of this type of information into electronic systems.

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<tr>
<td>Categorial structures for herbal medicaments - single natural materials and their formula</td>
<td>Australia has a strong academic and practice based traditional medicine culture. This work item is relevant to that community and to the integration of traditional medicine eventually into PCEHR and similar EHR systems and to support interoperability and research. Action: IT-014 to investigate appropriate input to these activities and to invite membership of relevant organisation/s to cover this new area of work.</td>
<td>IT-014</td>
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10.12 ISO 16277 STRUCTURE OF REPRESENTATION OF CLINICAL FINDINGS IN TRADITIONAL MEDICINE – PART 1: TRADITIONAL EAST ASIAN MEDICINE

The project to develop ISO 16277-1 Health informatics – Structure of representation of clinical findings in traditional medicine – Part 1: Traditional East Asian medicine passed NP ballot in May this year and the Traditional Medicine Task Force (TMTF) are currently working on development of a working draft with the scope of:

- Developing the reference terminology model and content model for describing patient findings
- Determining how to harmonize with biomedicine standards
- Justification of unique semantic links

It was agreed that work on metadata of categorical structure would be an excellent piece of work but beyond this project.

The resulting draft will be circulated for CD ballot with the end of February 2012 being the current target date. The Working Group requested a SNOMED CT expert from IHTSDO as a liaison officer to support this work item.
10.13 TRADITIONAL CHINESE MEDICINE METADATA AND SEMANTICS

The Traditional Medicine Task Force outlined two related areas of work relating to traditional Chinese medicine (TCM) metadata and semantics to be developed for balloting as new project (NP) proposals in the coming months as soon as suitable project proposals have been developed; they are:

- **Health informatics – Traditional Chinese medicine literature metadata**

  This New Project proposal is the more straightforward of the two and will define the metadata necessary to specify knowledge and publications related to TCM literature.

- **Health informatics – Semantic network framework and coding of literature of Chinese medicine language system**

  This work underpins the development of a ‘version of UMLS’ that represents TCM and which the WG members believed would underpin the capacity to mine TCM literature. This project relates directly to the first and seeks to address the inadequate support of TCM by existing language systems and semantic networks, particularly for the purpose of facilitating development of computer systems that behave as if they “understand” the meaning of the language of Chinese medicine. This development of computational semantics in TCM is already beginning.

The two NP proposals will be circulated to experts for review, when available.

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| **WG3 & TMTF**  
The academic TCM community in Australia is strong and would have a direct interest in this work.  
**Action**: Seek active engagement of the TCM academic community in Australia to provide input to these work items and to advise on our support, or otherwise of these work items. | IT-014 Standards Australia |
| **WG3 & TMTF**  
Semantic network framework & coding of TCM language systems | Proposed ISO/TS Semantic network framework and coding of literature of Chinese medicine language system. This work underpins the development of a ‘version of UMLS’ that represents TCM and which the WG members believed would underpin the capacity to mine TCM literature.  
The academic TCM community in Australia is strong and would have a direct interest in this work.  
**Action**: IT-014 to seek expert input on receipt of NP ballot for Semantic network framework and coding of Traditional Chinese Medicine language system, which is relevant to Australian interests in complementary medicine. | IT-014 Standards Australia |

11. **WG 4 – SECURITY, SAFETY AND PRIVACY**

| Australian Delegate Attendance | Michael Steine  
Occasional attendees for selected topics: - Richard Dixon Hughes |
11.1 GENERAL

Working Group 4 (WG 4) plays a vital role in progressing information security standards, including (where appropriate) encouraging finalization of standards on topics such as:

- Secure archiving of electronic health records;
- Privacy, use and disclosure of health information
- Security management in health information systems
- Audit trails for electronic health records;

The current office-bearers are:

- Convenor: Lori Reed-Fourquet, USA
- Vice Convenor: Luuc Posthumus, Netherlands
- Secretary: Elaine Sawatsky, Canada

11.2 PROGRESS OF PROJECTS

A large number of work items were on the agenda for this meeting, however many of these items were either NP or were items that have been stalled due to a lack of access to subject matter experts to progress the development of the documents.

Of significance to Australian interests in this meeting was the emergence of an NP around Digital Signatures (IS 17090.4) and the advancement to FDIS of ISO 21091 both which have direct relevance to items on the current program of eHealth work in Australia.

Of concern were a couple of items (new and existing) that are of questionable relevance to WG 4, specifically the work on Medical Privacy Officer Education and EHR Migration and also new items where the scope needs to be closely monitored (Consent).

11.3 STANDARDS PUBLISHED AND IN PUBLICATION

- ISO 21549-1 Patient health card data - Part 1: General structure (Revision submitted for publication following editorial corrections Standards published and in publication
- ISO/TS 14265 Classification of purposes for processing of personal health information (After additional editing re-sent to ISO/CS in May 2011 and is awaiting publication.

11.4 ISO 21091 - DIRECTORY SERVICES FOR HEALTH CARE PROVIDERS, SUBJECTS OF CARE AND OTHER ENTITIES

The work on ISO 21091 Directory services for health care providers, subjects of care and other entities proposes to deliver a standard approach for directory services to facilitate the retrieval, location and update of health information.

The DIS ballot resulted in 57 comments being received, primarily from Canada and Sweden. Austria also commented that the document needed alignment with SKMT to make it more consistent. Many of the other comments related to the consistency of definitions throughout the document in relation to items such as integrity and authentication.
WG 4 agreed that it should not try to create new terms and definitions (especially in the security space, where well known and agreed terms exist across the sector, specifically those used in the ISO/IEC 27000-series of information systems security standards) but, rather, it should be adopting and applying definitions and terms from the relevant sources.

Subsequently the majority of the feedback on definitions was persuasive and appropriate actions were set in train to correct and align definitions.

Another comment related to the inclusion of the ‘Religion’ field in the directory. This raised some concern as it was understood in certain realms that this attribute may be sensitive or in some cases prohibited. It was pointed out that it is not the role of the standard to dictate what appears in a implementation but if implemented, it should cover how the attribute is applied. A statement was added that each attribute should be reviewed by the implementer to determine whether or not it is required in the directory and the appropriate permissions to use and access the information considered.

All other changes were accepted and it was agreed to send the revised document out for FDIS ballot.

Relevance to Australia

Victoria’s Health Services Directory is playing a key role in the development of a National Health Services Directory. The ISO 21091 standard will have an effect on the way that international software providers design and consume directory services and should be reviewed for alignment with these current projects in Australia. It is also a concern that the ISO standard constrains a directory service in a way that makes it un-implementable in Australia due to issues such as privacy.

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<th>Topic</th>
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<tr>
<td>WG4 Security, privacy &amp; Safety</td>
<td>ISO/FDIS 21091 Directory services for health care providers, subjects of care and other entities may directly affect present and planned health service directory implementations in Australia. There may be some privacy aspects that need to be assessed in the standard. <em>Action: IT-014-06 and IT-014-04 to review FDIS for any issues that would adversely affect existing or planned directory services implementations in Australia.</em></td>
<td>IT-014-06 IT-014-04</td>
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<td>ISO FDIS 21091 Directory services</td>
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11.5 ISO 17090 PUBLIC KEY INFRASTRUCTURE

The ISO 17090-series of PKI standards for managing PKI security in healthcare was one of the first standards published in ISO Security (2002) and has been periodically reviewed to ensure the document is up to date, current and relevant to the standards committee as per ISO/TC 215 protocols. The three documents that currently comprise the ISO 17090-series are:

- **ISO 17090-1:2008 Health informatics - Public key infrastructure - Part 1: Overview of digital certificate services**
  (Note: 2008 edition revises 2002 edition which is adopted without change in the Australian Standard AS ISO 17090-1)
- **ISO 17090-2:2008 Health informatics - Public key infrastructure - Part 2: Certificate profile**
  (Note: 2008 edition revises 2002 edition which equates to AS ISO 17090-2)
- ISO 17090-3:2008 Health informatics - Public key infrastructure - Part 3: Policy management of certification authority

The three documents have been subjected to a periodic review and are in the process of again being updated to produce contemporary revisions of all three parts.

During the review survey there was general support to retain and update the standards but Canada abstained on the basis that the standard is no longer widely used and is not considered the national approach there.

It was noted that Australia had indicated in the ballot survey that this standard was not used or planned to be used in Australia. It was clarified that this was incorrect; it has been locally adopted as AS ISO 17090 parts 1 to 3 which directly reflect these standards and will be used by the NASH project.

In Part 1 - There was a discussion on the inclusion of a section on key escrow. It was noted that key escrow is only one aspect of key management and that key management can occur in a number of ways and there are various approaches other than key escrow. There are also many different business needs for key management from short term security to long term prevention of data loss. Therefore it was decided that it was necessary to state that a form of key management was a necessary part of a PKI strategy (and that this is not specifically only key escrow). Otherwise the recommendation was to renew the standard.

On the motion to renew Part 2 of the standard, the only further comments and recommended change came from Finland and The Netherlands who sought to change the role (hcRole attribute) on identity credentials from a mandatory to an optional extension. In those two countries, which are using the standard, it is optional.

For Part 3, there were no comments or recommendations to revise the standard and it therefore will remain as is.

At the May meeting in Kuopio there was a proposal from Japan to add a Part 4 on digital signatures for healthcare documents (see next section). This will have an impact on Part 1 as it will need to be harmonised with the content of Part 4. It is important to note that, at this time, Part 1 cannot be amended to reflect any of the work from Part 4 until ratified and as it may take 12-18 months for Part 4 to pass through the process it was agreed to proceed and to amend Part 1 at a later stage to align with Part 4 if it is published.

The revised ISO 17090 Parts 1, 2 and 3 will now be circulated for DIS ballot

Relevance to Australia

AS 17090 parts 1 to 3 were published in 2003 by Standards Australia and will need to be revised to align with this planned revision and also any work from the NASH program. Elements of the NASH program may also be required to filter back up into the DIS ballot.

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<tr>
<td>WG4</td>
<td>Australia will need to respond to the DIS ballot on ISO 17090. AS 17090 parts 1-3 were published in 2003 by Standards Australia and will need to be revised to align with this revision. <strong>Action</strong>: NEHTA and IT-014-04 to continue involvement and monitor changes and impact on AS/ISO 17090 1-3 and harmonisation with current NASH work.</td>
<td>IT-014-04 NEHTA</td>
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11.6 ISO/NP 17090 PART 4 – DIGITAL SIGNATURES

A new work item was proposed by the Japanese delegation to develop ISO 17090 Health informatics – Public key infrastructure – Part 4: Digital signatures for healthcare documents to complement the three existing ISO 17090 PKI documents discussed in the previous section.

This NP is based on the ETSI 101733 (CadES) and 101903 (XadES) Electronic Signature standard, which is also an ISO FDIS and likely to become an international standard in the near future. Concerns were raised about baselining on the ETSI standard however it was pointed out that the ETSI work is on trajectory to become an ISO standard without much variation or at least the variation would be known by the time of this document’s publication. It was also requested that IHE Dsig work be referenced as a relevant document to review in developing this standard.

Debate over the scope was raised concerning the title of the NP and there was discussion as to whether the scope should be Electronic Signature or Digital Signature. Electronic Signature can and is associated in other standards documents with any signature that has an electronic representation. This can mean a signature that has been scanned, faxed, captured using an electronic pen or a PKI digital signature.

As the scope referred only to digital signatures and is also used only for the signing and verification of documents within the healthcare sector, the title was revised to “Digital signatures for healthcare documents”.

WG 4 also noted that it will be necessary to to define why a signature is used and when and this may require some additional vocabulary to be defined and harmonised.

The calling of an NP ballot for this project was approved and a committee draft is planned to be ready to discuss at the next meeting in May 2011 along with any comments from the NP ballot.

Relevance to Australia

Progress on this item needs to be reviewed and closely monitored by IT-014 to see that this is in alignment with current work occurring in Australia by NEHTA in relation to digitally signing CDA documents which is using an attached signature based on the XML-Dsig. XML-Dsig is a general framework for digitally signing documents, whereas XadES specifies precise profiles of XML-Dsig in the ETSI standard. Therefore there is need to understand that the profiling of XML-Dsig done by NEHTA is consistent with the approach specified in the ETSI standard.

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<tr>
<td>WG4 NP ISO 17090 Part 4 Digital Signatures</td>
<td>Progress on this item needs to be reviewed and closely monitored by IT-014 to see that this is in alignment with current work occurring in Australia by NEHTA in relation to digitally signing CDA documents. Action: NEHTA, IT-014-06 and IT-014-04 to continue involvement and monitoring of impact of ISO 17090-4 Digital Signatures for healthcare documents on current work.</td>
<td>NEHTA IT-014-06 IT-014-04</td>
</tr>
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</table>
11.7 REQUIREMENTS FOR CONSENT FOR THE COLLECTION, USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION

The overall objective of this new work item is to provide sufficient meaning to the concept of 'consent' in the context of collecting, using and disclosing personal health information to allow organizations to appropriately apply a fair and meaningful approach to the application of a consent process. The proposed document is a technical specification:

- ISO/TS Health Informatics – Requirement for consent for the collection, use and disclosure of personal health information

Keeping in mind that the goal is the establishment of mutual, appropriate trust, a patient who is not informed, cannot provide meaningful consent, and thus has no opportunity to develop an appropriately trusting relationship with the steward of their data be that a physician, ministry, or private enterprise.

There was significant discussion on this NP, primarily that the notion of consent is considered very different between realms. It was felt that this item should not be a Technical Specification (as per the current NP) and should be a Technical Report. However there were concerns that if this is just a TR than it closes the door on realising specific normative ways to capture consent structures.

HL7 has constructs for consent such as the communication of obligations to restrict release of information beyond its disclosure. This work is been conducted by the HL7 Security Working Group and the NP needs to include reference to this work.

The calling of an NP ballot was approved, and a committee draft is planned for the next WG meeting in May 2011.

Relevance to Australia

There are a number of concerns about the scope of this item and the implication of constraint that a standard may place on other legal and local aspects of consent. It is recommended that this item be closely monitored and scrutinised as to ensure only relevant content at an international level is standardised. It is still also debatable if this should remain as a TS or revert to an TR.

The obsolete but often used AS 4400:1995 Personal privacy protection in health care information systems faced many similar challenges and may provide some guidance for this work.

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<tr>
<td>WG4 New work on requirements for consent</td>
<td>There are a number of concerns about the scope of the proposed NP on Requirements for Consent for the Collection, Use and Disclosure of Personal Health Information and the implied constraints that such a standard may place on other legal and local aspects of consent, use and disclosure of health information. The obsolete but often used AS 4400:1995 Personal privacy protection in health care information systems faced many similar challenges and may provide some guidance for this work. <strong>Action: IT-014 to continue involvement and monitoring of this NP.</strong></td>
<td>IT-014</td>
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11.8 MEDICAL PRIVACY OFFICER EDUCATION

A proposal for a new project was put forward by the Korean delegation suggesting the development of a technical report (TR) on "Medical privacy officer education". It aims to address the educational
components needed to protect the privacy of medical information reflected characteristics of health service and EMR.

It is proposed this work will be of interest to healthcare educators, educational facilities, administrators and countries planning to deploy compliance process for Medical Privacy Officers.

Discussion centred on whether the competency of Medical Privacy Officers is an appropriate subject for a WG 4 standard or indeed within the scope of TC 215 itself. In response it was raised that there is a requirement for agreement on these competencies to support trans-border work and information flows so that there is a basis on which the parties can be assured of the inherent competencies of staff dealing with information.

It was recommended that the current Korean specifications be presented so that the WG can review the documentation to understand the specifics of their scope and evaluate what aspects are appropriate for an ISO standard and if they are relevant to the WG4 scope.

WG 4 resolved that this was not yet ready for an NP ballot but, instead, had TC 215 register the topic as a Preliminary Work Item and requested the Korean delegation to present at the May 2011 WG on their current and proposed content.

Relevance to Australia

Many local policies and regulation may impact on the skill sets of a privacy officer therefore it is uncertain whether this body of work has a place within the ISO community. Therefore it is recommended to watch this item as it progresses to understand the relevance to Australia.

11.9 ISO/EN 16864 DATA PROTECTION IN TRANS-BORDER FLOWS OF PERSONAL HEALTH INFORMATION

ISO has a long history of developing standards in cross border data flows (both generically and in health), however there are now three standards documents which cover essentially the same content, healthcare data protection in trans-border flow of information.

Therefore the scope of this proposed standard is to merge three standards (ISO 22857, EN 14484, EN 14485) into a single deliverable:

- ISO 16864 Data protection in trans-border flows of personal health information (which would be a joint publication with CEN)

Other activities to be taken into account and harmonised with this work, where relevant, include:

- Update global context and terminology
- Generalise to “trans-jurisdictional borders”
- EN ISO 27799 harmonisation
- EHR access control “package”
- Pseudonymisation
- Patient consent developments

Changes of significance to the European Data Protection Act are anticipated, which will no doubt have a major impact on these standards.
This project is presently stalled due to administrative delays in a call for experts to participate in the project. There were only 4 experts nominated when the original NP was released and a new 30 day call for experts will come out towards the end of the year.

Relevance to Australia

This work is of growing relevance as jurisdictions look to provide trans-border access to EHR information.

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<tr>
<td>WG4 ISO/EN 16864 Data protection in trans-border flows of personal health information</td>
<td>Joint ISO/European work on ISO/EN 16864 Data protection in trans-border flows of personal health information is of growing relevance as jurisdictions look to provide trans-border access to EHR information. Nevertheless, this work item will not progress until relevant experts are found. <em>Action: IT-014 to seek an Australian expert to nominate for work on development of ISO 16864.</em></td>
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11.10 TASK GROUP ON HEALTH CARDS

A number of work items are in progress regarding Health Cards but many stalled due to a lack of subject matter experts. This is largely due to Health Cards being widely used but not high on the agenda of countries that have a large representation in WG 4 (Australia being one of them).

Most parts of the ISO 21549 series of health card standards (which define clinical content as well as identification information) were completed over ten years ago and have been widely applied particularly in some European and Asian countries including Russia. Parts 8 and 9 are more recent. Whilst they are relatively stable, these standards still need periodic review and update. The full 21549-series of standards is as follows:

- ISO 21549-1 *Health informatics - Patient healthcard data - Part 1: General structure*
  
  This first part of the ISO 21549 international standard defines data structures held on patient health cards that comply with the physical dimensions of ID-1 cards defined by ISO 7810 and gives a general structure for the different types of data defined in separate parts of the standard.
  
  A recent revision has been submitted for publication following editorial corrections and is awaiting publication.

- ISO 21549-2 *Health informatics - Patient healthcard data - Part 2: Common objects.* Updated material has been submitted for CD ballot and is awaiting resources to review the CD ballot results

- ISO 21549-3 *Health informatics - Patient healthcard data - Part 3: Limited clinical data.* Updated material has been submitted for CD ballot and is awaiting resources to review the CD ballot results

- ISO 21549-4 *Health informatics - Patient healthcard data - Part 4: Extended clinical data.* Updated material has been submitted for CD ballot and is awaiting resources to review the CD ballot results

With respect to the review of CD ballot responses for parts 2, 3 and 4, there is a lack of experts available, with only 4 member countries agreeing to participate, therefore at this time they cannot resolve the ballot comments even though the work to resolve is likely to be quite trivial.
- ISO 21549-5 *Health informatics - Patient healthcard data - Part 5: Identification data*. Currently in systematic review

- ISO 21549-6 *Health informatics - Patient healthcard data - Part 6: Administrative data*. Currently in systematic review

- ISO/FDIS 21549-7 *Health informatics - Patient healthcard data - Part 7: Medication data*

Several comments have been received pertaining to the FDIS for a new edition of the medication data standard.

There is a lack of experts available for this project, with only 4 member countries agreeing to participate. A significant number of countries have no intention of storing medication data on health cards however it is done in Italy and Spain and they may be able to contribute. The Italian delegate agreed to check with their body to see if they can provide an expert. The possibility of moving this aspect of health cards to the Pharmacy WG was also considered.

- ISO 21549-8 *Health informatics - Patient healthcard data - Part 8: Links*. First published in 2010

- ISO 21549-9 *Health informatics - Patient healthcard data - Part 9: Health Data*.

In 2008, China (PRC) proposed that a Part 9 of the health cards standard be used for recording health, wellness and lifestyle data as well as the disease information already accommodated. A more detailed proposal does not seem to have been received and this Part, although proposed, does not seem to have been registered as an active work item.

The other relevant health cards standard is ISO 20301:2006 *Health Informatics – Health Cards – General Characteristics*. The production of a second edition of this standard is a current work item. Experts have been nominated but it requires one additional expert to progress.

**Relevance to Australia**

This work is of not of significant interest to Australia at this point in time as there is no significant direction towards storage of health information on cards in Australia.

### 11.11 ISO 27799 INFORMATION SECURITY MANAGEMENT IN HEALTH USING ISO/IEC 27002

ISO 27799 *Health informatics - Information security management in health using ISO/IEC 27002* was initially published in 2006 and voting for systematic review was conducted in April. Much of the review comment related to the current revision to the underlining ISO/IEC 27002 standard. The ISO 27002 standard is the second standard in the ISO/IEC 27000 family of information security standards. It provides a comprehensive set of information security control objectives and a set of generally accepted security controls and good practices that can be audited against.

Australia made significant comments to the review and it was acknowledged in the meeting that the feedback received was of significant and high value. One of the key issues is how to synchronise with proposed changes to ISO/IEC 27002.

The WG was presented with 4 options as to the progress of this item as a result of the systematic review:

- Do nothing (keep standard as published)
- Take on board recommendations (and other comments) into a new version
- Perform full revision including ISO/IEC 27001 and the review comments
• Wait until the underlying revision of the ISO/IEC 27000 series of standards is complete

It was agreed that there would need to be further discussion around these options to determine the way forward as several countries were at differences over the approach. This will happen via list discussion prior to the May 2011 WG meeting with a view to setting the direction at that meeting.

Relevance to Australia

Australia supplied a number of comments to the systematic review. It was the Australian delegation recommendation to proceed to a new revision as soon as possible as significant effort had been done in this area locally and that the healthcare sector was also one of the foremost adopters of the ISO/IEC27000 series and that we should be seen to be moving forward with the standards.

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| WG4 ISO 27799 Information security management in health using ISO/IEC 27002 | Still to be determined the course of action taken as a result of the review, whichever way it progresses a team of experts is required and Australia has stated we will provide to progress the re-issue of this standard.  
**Action:** IT-014-04 to seek an Australian expert to nominate for work on development of ISO 27799. | IT-014-04 |

11.12 DTR 16114 - SECURITY ASPECTS OF EHR MIGRATION

The focus of the work on the technical report *ISO/TR 16114 Security aspects of EHR migration* is security aspects of data migration of EHRs in healthcare settings. The basic form of migration discussed here is the migration of the EHRs in the form of a document, but the impact the transfer of meta-information such as data structures, links, views, data processing rules, security and privacy protection policies also need to be discussed.

A draft of this work item was planned for the last meeting in Kuopio but was delayed until this meeting.

A problem still unsolved is that during its lifetime EHR content may move between different operating environments (software) or hardware platforms and what the accepted need is when applying security consistently during migration across these different platforms.

The content of the report is more focused on end-to-end data migration activities rather than specific security aspects. This is an acknowledgement that security impacts many on the other activities but also led to discussion about whether this document is more suited to being a joint work item with WG8 in an EHR context rather than just a security item.

WG4 is looking for comments on the DTR by December and there were no resolutions for this meeting. March 30th is the deadline for any draft documents for discussion at the May 2012 meeting.

Relevance to Australia

This document will seek to provide guidance to those looking to migrate data from one EHR system to another. The removal of any barriers in this area should be seen as a positive initiative to the stakeholders in the eHealth sector in Australia and therefore we should be supportive of this project. As stated though there are questions over its place solely within the Security realm.
11.13 ISO/TS 22600 - PRIVILEGE MANAGEMENT AND ACCESS CONTROL

ISO/TS 22600 Privilege Management and Access Control (PMAC) is a three part specification with
and reviewed in 2010. Part 3: Implementations, was published 2009.

At this point PMAC is a technical specification and generally accepted a important work. Current work
is aimed at bringing the three parts together into a single document to be published as a full
international standard, ISO 22600 Health informatics - Privilege management and access control.

In the 2010 Rotterdam WG (and reaffirmed in Kuopio WG) agreement was reached to combine all three
parts of the documents into a single document. Work has now started upon this and challenges exist in
removing duplication and applying consistency to the target document from the three sources.

Significant feedback came from Canada however this was mostly editorial and minor technical. These
changes were accepted and agreed to progress the document to a final review for the May 2012
meeting.

Relevance to Australia

The PMAC specifications are not widely adopted in Australia, however a number of the core concepts
are relevant and present in most activities under the national eHealth agenda. It would be a worthwhile
exercise for Australia to review the draft to understand how it sits within the broader context of other
health IT security standards and initiatives such as NASH in Australia.

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<tr>
<td>WG4 DTS 22600 PMAC</td>
<td>It is unclear exactly where the work on PMAC and its revision to a full international standard sits in the Australian context of IT security standards and work such as NASH. Action: Recommend IT-014-04 review the Draft document to seek an Australian position on the publication and the relevance of adopting this locally.</td>
<td>IT-014-04 NEHTA</td>
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11.14 DTS 14441 SECURITY & PRIVACY REQUIREMENTS OF EHR SYSTEMS FOR USE IN CONFORMITY ASSESSMENT

As countries begin to connect clinical systems to EHR infostructure (or directly exchange clinical
information with other clinical systems through system-to-system communications) to enable electronic
prescribing, access to diagnostic results and the exchange of patient information between care
locations, the security and privacy of these systems becomes much more critical and complex than
when the systems operated in a disconnected or ‘stand-alone’ state.

Work on technical specification ISO/TS 14441 Security & privacy requirements of EHR systems for use in conformity assessment (originally in two parts) seeks to outline concepts, methods and examples of conformity assessment of the security and privacy requirements in this system-to-system environment.

WG 4 reviewed the current working draft of the proposed technical specification.

It was discussed that there is current work in the HL7 EHR functional Model in this area and in ways
this work is more advanced and should be fed into the HL7 WG for consideration.
Part 2 Annex B “Examples of scripts for testing” is recommended to be removed as the effort to create them is considerable and their questionable accuracy and value out of context is a risk to users of the document. The generic advice about testing will be included in a Part 1 Annex that has content on conformity assessment.

It was determined to remove Part 2 and only have single document in the standard. This involves moving the 66 detailed requirements from the second document and merging them into the first and this make take a little time and effort.

The working draft is to be refined into a single document and released for final review by the May 2012 WG meeting.

Relevance to Australia

Australia will be implementing certification and conformance testing programs around the PCEHR. Compliance with these requirements may be a desirable goal for our national program as they mature to publication.

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<td>WG4 Security: DTS 14441</td>
<td>It is unclear exactly where DTS 14441 Security &amp; privacy requirements of EHR systems for use in conformity assessment (Parts 1 &amp; 2) sits in the Australian context of IT security standards and work such as NASH and our CCA activities. Action: IT-014-04 to review the Draft document to seek an Australian position on the publication and the relevance of adopting this locally.</td>
<td>IT-014-04 NEHTA</td>
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11.15 ISO 27789 AUDIT TRAILS FOR ELECTRONIC HEALTH RECORDS

ISO 27789 Health informatics - Audit trails for electronic health records (currently at DIS stage) is strictly limited in its scope to the logging of events. Changes to data values in fields of an EHR are presumed to be recorded in the EHR database system itself and not in the audit log. It is also presumed that the EHR system itself contains both the previous and updated values of every field. This is consistent with contemporary point-in-time database architectures. The audit log itself is presumed to contain no personal health information other than identifiers and links to the record.

A second DIS ballot due to administrative issues such as translation into German and French prior to release and therefore this is held up at the secretariat level. Once resolved it will be released for a 2 month ballot and target resolution to send for FDIS for May WG in Vancouver. Therefore there will be a meeting (via GoToMeeting) in April 16th (12:00 UTC) to review comments from the ballot prior to the WG.

There will be a meeting (via GoToMeeting) in April 16th (12:00 UTC) to review comments from the ballot prior to the WG.

Relevance to Australia

Effective audit and logging can help to uncover misuse of EHR systems or EHR data and can help organisations and subjects of care obtain redress against users abusing their access privileges. For auditing to be effective, it is necessary that audit trails contain sufficient information to address a wide
variety of circumstances. It will be an expectation that EHR systems such as the proposed PCEHR and will need to ensure compliance with these standards in the future.
12. TC 215 CLOSING PLENARY

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<tr>
<th>Australian Delegate Attendance</th>
<th>Richard Dixon Hughes (Head of Delegation)</th>
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<tr>
<td></td>
<td>Heather Grain (WG 3 convener)</td>
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<td>Naomi Ryan (WG 8 secretariat)</td>
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<td>David Rowed, Heather Leslie, David Rowlands, Michael Steine, Janette Gogler</td>
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The closing plenary addressed the following agenda, with all resolutions being separately recorded in section 13 below.

1. Opening of meeting
   - Dr. Chris Chute
2. Recognize Observing Members who participated in the meeting
   - Ms. Lisa Spellman
3. Recognize Liaisons who participated in the meeting
   - Ms. Lisa Spellman
4. Roll Call of ISO/TC 215 Participating Member Delegates
   - Ms. Lisa Spellman
5. Adoption of agenda
   - Dr. Chute
   - Dr. Chute
   6.1 Re-Organization Interim Report
      - Mr. Jeremy Thorp
7. Joint Initiative Council (JIC) Report
   - Mr. Bron Kisler (CDISC), JIC Chair
8. Reports [and resolutions] from the Working Groups
   - WG conveners
9. TC 215 long term calendar development – 3-5 year
   - Ms. Lisa Spellman
10. Other Business
11. Approval of Meeting Resolutions
12. Adjournment (Close of meeting)

Upcoming meetings

- 2012 - Plenary – May 6-10, 2011, Vancouver, BC Canada
- 2012 - WG: Austria – tentative (in conjunction with CEN/TC 251)
- 2013 – Plenary: Host site sought (Japan had been mentioned at one point)
- 2013 – WG: Host site sought (in conjunction with CEN/TC 251)
- 2014 – Plenary – Host site sought (China had been mentioned at one point)
- 2014 – WG - Host site sought
- 2015 – Plenary: Host site sought
- 2015 – WG: Host site sought
- 2016 – Plenary: Host site sought
- 2016 – WG: Host site sought
- 2017 – Plenary: Host site sought
- 2017 – WG: Host site sought
13. RESOLUTIONS FROM TC 215 PLENARY

13.1 BACKGROUND

Resolutions for the plenary session are drafted by the working groups, task forces and other constituent bodies within TC 215 and typically follow wording set out in common templates circulated by the TC 215 Secretariat. The resolutions were circulated to national delegations for review shortly before the final plenary.

Contentious issues tend to be raised and discussed during WG sessions or, at the latest, when the proposed resolutions are circulated to the national delegations with consensus on most matters being achieved by negotiation before they are presented to the plenary. Under this process, while some items are contested on the floor of the plenary, it is normal for the vast majority of resolutions to be passed.

13.2 RESOLUTIONS APPROVED

The following resolutions were approved at the closing plenary session – with specific Australian involvement being noted, where relevant.

Notes:

1. In our reporting on resolutions below, the words "Health informatics" in document titles have usually been abbreviated to "HI", except where this might cause confusion.

2. Copies of the draft resolutions circulated prior to the final plenary sessions and many WG slide presentations contain "contingency" resolutions that were not subsequently put to or passed by TC 215. Care should be taken only to use the finally approved resolutions as reported below.

3. Some minor typographical and citation errors and inconsistencies have been corrected.

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<thead>
<tr>
<th>Resolution</th>
<th>Further action/comment</th>
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<tr>
<td>1. <strong>Resolved</strong>, that ISO/TC 215 accepts the report of TC 215 Working Group 1</td>
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<td>2. <strong>Regarding</strong> ISO/HL7 NP 13972-1 Health Informatics - Detailed Clinical Models - Part 1: Quality processes regarding detailed clinical model development, governance, publishing and maintenance <strong>Resolved</strong> that ISO/TC 215: <strong>Notes</strong> that ISO NP 13972 is listed as critical in the ISO Project Portal and will be cancelled in January 2012 if the project does not progress; <strong>Requests</strong> its Secretary to submit an extension request to the ISO Technical Management Board, citing appropriate reasons for the delay no later than 26 October 2011;</td>
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### Resolution

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<th>Resolution</th>
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<tr>
<td>Agrees to progress this item to a 3 month CD ballot, for vote and comment;</td>
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<tr>
<td>Asks the PL/WG convener to provide the final CD text, updated to reflect input agreed by WG 1, to the Secretary no later than 28 October 2011;</td>
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<tr>
<td>Recognizes that this is a VA item with ISO lead; and</td>
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<tr>
<td>Instructs its Secretary to coordinate with CEN/TC 251 to prepare and issue the CD ballot no later than 15 November 2011.</td>
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   Resolved that ISO/TC 215:

   - Confirms that this work item will be issued in 2 parts;
   - Requests its Secretary to ensure the work item is properly registered with ISO/CS, to reflect that it is intended as a standard with 2 parts;
   - Agrees to progress this item to a 3-month CD ballot, for vote and comment;
   - Asks the PL/WG convener to provide the final CD text, updated to reflect input agreed by WG 1, to the Secretary no later than 15 November 2011;
   - Recognizes that this is a VA item with ISO lead; and
   - Instructs its Secretary to coordinate with CEN/TC 251 to prepare and issue the CD ballot no later than 30 November 2011.


   Resolved that ISO/TC 215:

   - Approves the WG 2 recommendation to issue a new work item proposal ballot to seek approval to progress HL7 Reference Information Model, Release 4 under the fast-track approach,
   - Instructs its secretariat to submit, should the NP be approved, within four weeks of the closing date of the NP ballot, a DIS text to the ISO/CS for distribution.


   Resolved that ISO/TC 215:

   - Approves the WG 2 recommendation to circulate a new work item targeting a technical report to ISO/TC 215 for review and comment;
   - Asks the PL/WG convener to provide the draft TR text to the secretariat no later than 28 November 2011;
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<th>Resolution</th>
<th>Further action/comment</th>
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<tr>
<td><strong>Instructs</strong> its secretary to circulate the NP ballot no later than 11 December 2011.</td>
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<tr>
<td><strong>Approves</strong> the WG 2 request for the WG2 joint TC 215/DICOM project team to add the first four ISO document clauses to the WADO-WS document;</td>
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<td><strong>Asks</strong> the PL/WG convener to provide the text to the Secretary no later than 29 February 2012;</td>
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<tr>
<td><strong>Instructs</strong> its Secretary to request, no later than 11 March 2012, the ISO/CS to issue a DIS ballot.</td>
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<tr>
<td>9. <strong>Regarding</strong> Health informatics – Categorical structure for representation of herbal medicaments in terminological systems <strong>Resolved</strong> that ISO/TC 215:</td>
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<tr>
<td><strong>Approves</strong> the WG 3 recommendation to issue NP ballot targeting a technical specification;</td>
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<td><strong>Asks</strong> the PL/WG convener to provide the secretariat with a completed Form 4 and text no later than 31st October 2011;</td>
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<tr>
<td><strong>Instructs</strong> its Secretary to issue a NP no later than 17th November 2011.</td>
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<tr>
<td>10. <strong>Regarding</strong> Health informatics - Traditional Chinese Medicine Literature Metadata <strong>Resolved</strong> that ISO/TC 215:</td>
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<tr>
<td><strong>Approves</strong> the WG 3 recommendation to issue NP ballot targeting a technical specification,</td>
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<tr>
<td><strong>Asks</strong> the PL/WG convener to provide the secretariat with a text no later than 31st October 2011</td>
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<tr>
<td><strong>Instructs</strong> its Secretary to issue a NP no later than 17th November 2011.</td>
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<tr>
<td>11. <strong>Regarding</strong> ISO/NP 16277-1 HI – Structure of representation of clinical findings in traditional medicine – Part 1: Traditional East Asian medicine <strong>Resolved</strong> that ISO/TC 215:</td>
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<tr>
<td><strong>Accepts</strong> the WG 3 recommendation to progress the work item to a committee draft;</td>
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<tr>
<td><strong>Asks</strong> the PL/WG convener to provide the secretariat with a text no later than 28 January 2012</td>
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<tr>
<td><strong>Instructs</strong> its Secretary to issue a 2-month CD ballot no later than 15 February 2012.</td>
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<td>Resolution</td>
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<td>12. Regarding ISO/NP 13940 HI – System of concepts to support continuity of care [aka Contsys]</td>
<td>Resolved that ISO/TC 215: Accepts the WG 3 recommendation to progress the work item to a committee draft; Asks the PL/WG convener to provide the secretariat with a text no later than 30 November 2011; Instructs its Secretary to issue a 2-month CD ballot no later than 15 December 2011.</td>
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<tr>
<td>13. Regarding HI – Semantic network framework and coding of Traditional Chinese Medicine language system</td>
<td>Resolved that ISO/TC 215: Approves the WG 3 recommendation to issue NP ballot targeting a technical specification; Asks the PL/WG convener to provide the secretariat with a text no later than 31st October 2011; Instructs its Secretary to issue a NP no later than 17th November 2011.</td>
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<tr>
<td>15. Regarding ISO/DIS 21091 HI - Directory services for health care providers, subjects of care and other entities</td>
<td>Resolved that ISO/TC 215: Agrees to progress the work item to FDIS stage; Asks the PL/WG convener to provide the final text and disposition of comments to the Secretary no later than 1 November 2011; Instructs its secretariat to submit the FDIS to ISO/CS for circulation no later than 15 November 2011.</td>
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<tr>
<td>16. Regarding CD ISO 21549-2 Patient Health Card Data -- Part 2: Common objects</td>
<td>Resolved that ISO/TC 215: Agrees to progress the work item to DIS; Asks the PL/WG convener to provide the final text and disposition of comments to the Secretary no later than 1 November 2011; Recognizes that this is a VA item with ISO lead; and Instructs its Secretary to coordinate with CEN/TC 251 to submit the FDIS to ISO/CS for circulation no later than 15 November 2011</td>
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<tr>
<td>17. Regarding ISO 21549-3 “Patient Health Card Data -- Part 3: Limited clinical data”</td>
<td>Resolved that ISO/TC 215 Agrees to progress the work item to DIS;</td>
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<td>Resolution</td>
<td>Further action/ comment</td>
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<tr>
<td><strong>Asks</strong> the PL/WG convener to provide the final text and disposition of comments to the Secretary no later than 1 November 2011;</td>
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<tr>
<td><strong>Recognizes</strong> that this is a VA item with ISO lead; and</td>
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<tr>
<td><strong>Instructs</strong> its Secretary to submit the FDIS to ISO/CS for circulation no later than 15 November 2011.</td>
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<tr>
<td><strong>18. Regarding CD ISO 21549-4 “Patient Health Card Data -- Part 4: Extended clinical data****Resolved</strong> that ISO/TC 215:</td>
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<tr>
<td><strong>Agrees</strong> to progress the work item to DIS;</td>
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<tr>
<td><strong>Asks</strong> the PL/WG convener to provide the final text and disposition of comments to the Secretary no later than 1 November 2011;</td>
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<tr>
<td><strong>Recognizes</strong> that this is a VA item with ISO lead; and</td>
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<tr>
<td><strong>Instructs</strong> its Secretary to coordinate with CEN/TC 251 to submit the FDIS to ISO/CS for circulation no later than 15 November 2011</td>
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<tr>
<td><strong>Accepts</strong> the WG 4 recommendation, to revise this work item, based on the results of systematic review, and progress to committee draft</td>
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<tr>
<td><strong>Asks</strong> the PL/WG convener to provide the secretariat with a text no later than 1 November 2011</td>
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<tr>
<td><strong>Recognizes</strong> that this is a VA item with ISO lead; and</td>
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<tr>
<td><strong>Instructs</strong> its Secretary to coordinate with CEN/TC 251 to circulate a 2-month CD ballot no later than 1 December 2011</td>
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<td><strong>20. Regarding CD 20301 Health Informatics – Health Cards – General Characteristics****Resolved</strong> that ISO/TC 215:</td>
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<tr>
<td><strong>Agrees</strong> to progress the work item to DIS;</td>
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<tr>
<td><strong>Asks</strong> the PL/WG convener to provide the final text and disposition of comments to the Secretary no later than 1 November 2011;</td>
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<tr>
<td><strong>Recognizes</strong> that this is a VA item with ISO lead; and</td>
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<tr>
<td><strong>Instructs</strong> its Secretary to submit the FDIS to ISO/CS for circulation no later than 15 November 2011</td>
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<td><strong>21. Regarding CD 17090 Health informatics – Public Key Infrastructure – Part 1: Overview of digital certificate services</strong> <strong>Resolved</strong> that ISO/TC 215:</td>
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<tr>
<td><strong>Agrees</strong> to progress, based on the results of systematic review, the work item directly to DIS;</td>
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<tr>
<td>Resolution</td>
<td>Further action/ comment</td>
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</table>
| **22. Regarding** ISO/TS 17090 *Health informatics – Public Key Infrastructure – Part 2: Certificate profile*  
**Resolved** ISO/TC 215  
**Agrees** to progress, based on the results of systematic review, the work item directly to CD;  
**Asks** the PL/WG convener to provide the final text and disposition of comments to the Secretary no later than 1 November 2011;  
**Instructs** its Secretary to submit the DIS to ISO/CS for circulation no later than 15 November 2011 |
| **23. Regarding** ISO/TS 17090 *Health informatics – Public Key Infrastructure – Part 3: Policy management of certification authority*  
**Resolved** ISO/TC 215:  
**Agrees** to progress, based on the results of systematic review, the work item directly to DIS;  
**Asks** the PL/WG convener to provide the final text and disposition of comments to the Secretary no later than 1 November 2011;  
**Instructs** its Secretary to submit the DIS to ISO/CS for circulation no later than 15 November 2011 |
| **24. Regarding** NP 17090-4 Health informatics – Public Key Infrastructure – Part 4: Digital signatures for healthcare documents  
**Resolved** ISO/TC 215  
**Approves** WG 4 recommendation that to circulates the NP ballot for a new part 4;  
**Asks** the PL/WG convener to provide the text and form 4 to the Secretary no later than 1 November 2011;  
**Instructs** its Secretary to circulate the NP no later than 1 December 2011 |
| **25. Regarding** Requirements for EHR Privacy Officer Education  
**Resolved** ISO/TC 215:  
Approves the WG 4 recommendation that the secretary register this item as a preliminary work item, targeting a technical report. |
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<th>Resolution</th>
<th>Further action/comment</th>
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<tr>
<td>26. <strong>Regarding ISO/NP TS 14441-2, “Health informatics – Security and privacy requirements for compliance testing of EHR systems – Part 2: Protection profile for small scale patient health record systems</strong>&lt;br&gt;Resolved that ISO/TC 215:&lt;br&gt;Approves the WG 4 recommendation that this work item be withdrawn from the ISO/TC 215 program of work;&lt;br&gt;Instructs its Secretary to notify the ISO/CS no later than 31 October 2011.</td>
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<td>27. <strong>Regarding 14441-1 Security &amp; privacy requirements of testing of EHR systems for use in conformity assessment -- Part 1 — Foundations</strong>&lt;br&gt;Resolved that ISO/TC 215:&lt;br&gt;Approves the WG 4 recommendation that <strong>this work item be re-titled,</strong> “Health informatics – Security and privacy requirements for compliance testing of EHR systems”&lt;br&gt;Agrees to circulate the work item as a draft technical specification;&lt;br&gt;Asks the PL/WG convener to provide the secretary with a draft text no later than 1 December 2011;&lt;br&gt;Recognizes that this is a VA item with ISO lead; and&lt;br&gt;Instructs its Secretary to coordinate with CEN/TC 251 to circulate a DTS ballot no later than 21 December 2011.</td>
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<td>28. <strong>Regarding Health informatics - Principles and data structures for consent in the collection, use, or disclosure of personal health information</strong>&lt;br&gt;Resolved that ISO/TC 215:&lt;br&gt;Approves the WG 4 recommendation to circulate the NP ballot targeting a Technical Specification;&lt;br&gt;Asks the PL/WG convener to provide the secretariat with Form 4 and an outline document no later than 30 November 2011&lt;br&gt;Instructs its secretariat to circulate the NP no later than 21 December 2012.</td>
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<td>29. <strong>Resolved, that ISO/TC 215 accepts the report of Working Group 8</strong>&lt;br&gt;</td>
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<td>30. <strong>Regarding ISO TR 13054 HI – Knowledge management of health information standards</strong>&lt;br&gt;Resolved that ISO/TC 215:&lt;br&gt;Notes that WG 8 will conduct a four-week review of the draft technical report to solicit additional expert input;&lt;br&gt;Asks the PL/WG convener to provide the final TR text, updated to reflect input agreed by WG 8, to the Secretary no later than 7 December 2011;</td>
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<td>Resolution</td>
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<tr>
<td><strong>Instructs</strong> its Secretary to submit the final TR to the ISO/CS for publication no later than 15 December 2011.</td>
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<td><strong>31. Regarding ISO TR 14639-1 HI – Capacity-based ehealth architecture roadmap - Part 1: Overview of national ehealth initiatives</strong>&lt;br&gt;<strong>Resolved</strong> that ISO/TC 215:</td>
<td><strong>Notes</strong> that WG 8 will conduct a four-week review the draft technical report to solicit additional expert input;</td>
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<td><strong>Asks</strong> the PL/WG convener to provide the final TR text, updated to reflect input agreed by WG 8, to the Secretary no later than 7 December 2011;</td>
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<td></td>
<td><strong>Instructs</strong> its Secretary to submit the final TR to the ISO/CS for publication no later than 15 December 2011.</td>
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<td><strong>32. Regarding TC 215 Reorganization Task Force:</strong> Creation of a Reorganization Task Force to examine Chicago proposed work-items and named Richard Dixon-Hughes (AUS) as Task Force chair</td>
<td>ISO/TC 215 resolved that:</td>
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<td>Richard Dixon Hughes (AUS) is requested to investigate and report at the Vancouver 2012 plenary meeting on the possible methods of aligning the prioritisation, selection and approval of work items with TC 215 strategic objectives, including harmonisation and cohesiveness and that this work be undertaken in collaboration with the TC 215 Task Force on Re-organisation and Business Planning.</td>
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<td><strong>33. Resolved</strong> that ISO/TC 215 accepts the report of the TC 215 Executive Council [CAG]</td>
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<td><strong>34. Resolved</strong> that ISO/TC 215 accepts the report of the TC 215 Business &amp; Reorganization Task Force.</td>
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<td><strong>35. Resolved</strong> that ISO/TC 215 accepts the report of the Joint Initiative Council (JIC).</td>
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<td><strong>36. Regarding long-term meeting calendar planning process</strong></td>
<td><strong>Resolved</strong> that ISO/TC 215 approves the development of an ongoing long-term [3-5 year calendar] to help better manage and plan the work of the TC 215.</td>
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<td><strong>37. Regarding 2012 TC 215 meetings</strong></td>
<td>ISO/TC 215 resolved that the next ISO/TC 215 Plenary meeting will be held 5-9 May 2012 in Vancouver, Canada which is a slightly amended date from Kuopio Resolution 105 which was listed as 6-10 May 2012.</td>
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<td>ISO/TC 215 resolved to accept the invitation of the Austrian Standards Institute (ASI) to tentatively host the ISO/TC 215 Joint Working Group with Plenary the week of 24 September 2012 in Vienna, Austria.</td>
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13.3 RESOLUTIONS NOT APPROVED

No resolution presented to the closing plenary was not approved.

End of Report
APPENDIX A - ACRONYMS

ACCC Australian Competition and Consumer Commission
ACMA Australian Communication and Media Authority
ACSQHC Australian Commission on Safety and Quality in Health Care
ACTUG Australian Clinical Terminology Users Group
ADL Archetype Definition Language
AG Advisory Group
AHIMA American Health Information Management Association
AHMAC Australian Health Ministers’ Advisory Council
AHML Australian Healthcare Messaging Laboratory
AIHW Australian Institute of Health & Welfare
AIIA Australian Information Industry Association
AMT Australian Medicines Terminology
ANSI American National Standards Institute
ArB Architecture Review Board
AS HB Australian Handbook
AS/NZS Australian/New Zealand Handbook
AS/NZS ISO International Standards adopted by Australia and New Zealand
AWI Approved Work Item
CASCO Conformity Assessment
CBCC Community Based Collaborative Care Workshop
CCHIT (US) Certification Commission for Health Information Technology
CD Committee Draft (third stage in developing an ISO or IEC standard)
CDA Clinical Document Architecture
CDISC Clinical Data Standards Interchange Consortium
CDS Clinical Decision Support
CDV Committee Draft for Vote
CEN European Committee for Standardization
(Comité Européen de Normalisation)
CIC Clinical Interoperability Council Workgroup
CIS Clinical Information Systems
COAG Council of Australian Governments
DAFF Department of Agriculture, Fisheries and Forestry
DAM Domain Analysis Model (comprehensive model of a domain)
DCM Detailed Clinical Model
DCOR, COR (Draft) Corrigendum
DICOM Digital Imaging and Communications in Medicine
DIISR Department of Innovation, Industry, Science & Research
DIS Draft International Standard (fourth stage in developing an ISO or IEC standard – the main opportunity for public input)
DoHA (Australian Government) Department of Health and Ageing
DMP Dossier Médical Partagé (Shared Medical Record) (France)
DSTU Draft Standards for Trial Use (HL7 and ANSI)
EC European Commission [the administrative arm of the EU]
ECCF  Enterprise Compliance and Conformance Framework
EFMI  European Federation of Medical Informatics
EHR  Electronic Health Record
EHR-S  Electronic Health Record System
ELGA  Austrian CDA Implementation Guide in Development
ELS  End Point Location Service
EMEA  European Medicines Agency
EN  European Standard (Européen Norm)
ETP  Electronic Transfer of Prescriptions
EU  European Union
FDAM  Final Draft Amendment
FCD  Final committee draft
FDIS  [ISO] Final Draft International Standard (for vote to publish)
GCM  Generic Component Model
GDP  Gross Domestic Product
GP  General Practitioner
GS1  An international SDO – primarily in the supply-chain domain
HDF  HL7 Development Framework
HI  Health Identifiers
HIE  Health Information Exchange
HIMSS  Healthcare Information and Management Systems Society
HITSP  Health Information Technology Standards Panel
HL7  Health Level Seven (International)
HL7 ELC  HL7 E-Learning Course
HPI  Healthcare Provider Identifier
HPI-I  Healthcare Provider Identifier for Individuals
HPI-O  Healthcare Provider Identifier for Providers
HSSP  Healthcare Services Specification Project [joint HL7/OMG]
ICH  International Conference on Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use)
ICOGRADA  International Council of Graphic Design Associations
ICT  Information & Communications Technology
ICSR  Individual Case Safety Report [related to Medicines/Devices]
IDMP  Identification of Medicinal Products
IEC  International Electrotechnical Commission (an international SDO)
IEEE  Institute of Electrical & Electronic Engineers (US) (also an SDO)
IHE  Integrating the Healthcare Enterprise
IHI  Individual Healthcare Identifier
IHTSDO  International Health Terminology Standards Development Organisation
IS  International Standard
ISO  International Organization for Standardization
ISO/CS  ISO Central Secretariat
ITS  Implementable Technology Specifications
IXS  Identity Cross Reference Service
ITU-T  International Telecommunications Union – Standards Division
JI  Joint Initiative on SDO Global Health Informatics Standardization
JIC  Joint Initiative Council (responsible for governance of the Joint Initiative (JI) – with current members being ISO/TC215, CEN/TC251, HL7 International, CDISC, IHTSDO and GS1)
JTC  Joint Technical Committee
JTC 1  ISO/IEC Joint Technical Committee 1 Information Technology
JWG  Joint Working Group
KPI  Key Performance Indicator
LB  Letter Ballot
LMIC  Low and Medium Income Countries
LOINC  Logical Observation Identifiers Names and Codes
LPO  Local PCEHR Officer
MBS  Medical Benefits Scheme
MDA  Model Driven Architecture
MM  Maturity Model
MSIA  Medical Software Industry Association
NASH  National Authentication Service for Health
NATA  National Association of Testing Authorities
NEHTA  (Australian) National E-Health Transition Authority
NH&MRG  National Health and Medical Research Council
NHIN  (US) National Health Information Network
NHISSC  National Health Information Standards and Statistics Committee
NIH  (US) National Institutes of Health
NIST  National Institute of Standards and Testing
Normapme  European Office of Crafts, Trades and Small and Medium sized Enterprises for Standardisation
NMB  National Member Body [of ISO or CEN]
NP  New Work Item Proposal (current ISO/IEC abbreviation)
NPACC  National Pathology Accreditation Advisory Council
NSO  National Standards Office
NP  New Work Item Proposal (obsolete ISO/IEC abbreviation – see "NP")
OBPR  Office of Best Practice Regulation
OCL  Object Constraint Language
OID  Object Identifier
OMG  Object Management Group
ONC  Office of the National Coordinator for Health Information Technology (within US Department of Health and Human Services)
O&O  Orders and Observations Workgroup
OSI  Open Systems Interconnection
OTF  Organisation Task Force [ISO TC 215]
OWL  Web Ontology Language
PACS  Picture Archive Systems
PAS  Patient Administration Systems
PDAM, DAM  (Proposed) Draft Amendment
PDF  Portable Document Format
PDTR, DTR  (Proposed) Draft Technical Report
PBS  Pharmaceutical Benefits Scheme
PCEHR  Personally Controlled Electronic Health Record
PHDSC  Public Health Data Standards Consortium
<table>
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<th>Abbreviation</th>
<th>Full Form</th>
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<tr>
<td>PHR</td>
<td>Personal Health Record</td>
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<td>PHR-S</td>
<td>Personal Health Record System</td>
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<tr>
<td>PHTF</td>
<td>Public Health Task Force</td>
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<tr>
<td>PIM</td>
<td>Platform Independent Model</td>
</tr>
<tr>
<td>PIP</td>
<td>Practice Incentive Payment</td>
</tr>
<tr>
<td>PIR</td>
<td>Post Implementation Review</td>
</tr>
<tr>
<td>PKI</td>
<td>Public Key Infrastructure</td>
</tr>
<tr>
<td>PM</td>
<td>Project Manager</td>
</tr>
<tr>
<td>PMBOK</td>
<td>Project Management Body of Knowledge</td>
</tr>
<tr>
<td>PMS</td>
<td>Practice Management System</td>
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<tr>
<td>PMTL</td>
<td>Project Management Team Leader</td>
</tr>
<tr>
<td>PoC</td>
<td>Point-of-Care</td>
</tr>
<tr>
<td>PSM</td>
<td>Platform Specific Model</td>
</tr>
<tr>
<td>RACGP</td>
<td>Royal Australian College of General Practice</td>
</tr>
<tr>
<td>RCPA</td>
<td>Royal College of Pathologists Australia</td>
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<tr>
<td>RHIO</td>
<td>(US) Regional Health Information Organisation</td>
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<tr>
<td>RIMBAA</td>
<td>RIM Based Application Architecture</td>
</tr>
<tr>
<td>RIM</td>
<td>Reference Information Model</td>
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<tr>
<td>RIS</td>
<td>Radiology Information Systems</td>
</tr>
<tr>
<td>RLUS</td>
<td>Resource Locate Update Service (HSSP)</td>
</tr>
<tr>
<td>RM-ODP</td>
<td>Reference Model of Open Distributed Processing</td>
</tr>
<tr>
<td>SA</td>
<td>Standards Australia</td>
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<tr>
<td>SAIF</td>
<td>Services Aware Interoperability Framework</td>
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<tr>
<td>SC</td>
<td>Subcommittee</td>
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<tr>
<td>SDO</td>
<td>Standards Development Organisation</td>
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<tr>
<td>SIG</td>
<td>Special Interest Group</td>
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<tr>
<td>SKMT</td>
<td>Standards Knowledge Management Tool</td>
</tr>
<tr>
<td>SLA</td>
<td>Service Level Agreement</td>
</tr>
<tr>
<td>SME</td>
<td>Subject Matter Experts</td>
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<tr>
<td>SMTP</td>
<td>Simple Mail Transfer Protocol</td>
</tr>
<tr>
<td>SNOMED</td>
<td>Systematised Nomenclature of Medicine</td>
</tr>
<tr>
<td>SOA</td>
<td>Service Oriented Architecture</td>
</tr>
<tr>
<td>SOAP</td>
<td>Simple Object Access Protocol</td>
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<tr>
<td>TC</td>
<td>Technical Committee</td>
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<tr>
<td>TCM</td>
<td>Traditional Chinese Medicine</td>
</tr>
<tr>
<td>TCP/IP</td>
<td>Transmission Control Protocol/Internet Protocol</td>
</tr>
<tr>
<td>TEAM</td>
<td>Traditional East Asian Medicine – This term, though inadequate is used to represent Traditional Chinese Medicine, Traditional Korean Medicine, Traditional Japanese Medicine.</td>
</tr>
<tr>
<td>TF</td>
<td>Task Force</td>
</tr>
<tr>
<td>TM</td>
<td>Traditional Medicine</td>
</tr>
<tr>
<td>TOGAF</td>
<td>The Open Group Architecture Framework</td>
</tr>
<tr>
<td>TR</td>
<td>Technical Report (an informative ISO or IEC standards publication)</td>
</tr>
<tr>
<td>TS</td>
<td>Technical Specification (a normative standards publication having a lower level of consensus than a full international standard)</td>
</tr>
<tr>
<td>UCUM</td>
<td>Unified Code for Units of Measure [© Regenstrief Institute]</td>
</tr>
<tr>
<td>UML</td>
<td>Unified Modelling Language</td>
</tr>
<tr>
<td>UN</td>
<td>United Nations</td>
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</tbody>
</table>
VA   Vienna Agreement (between ISO and CEN for joint development of European and International standards)
VMR  Virtual Medical Record
W3C  World Wide Web Consortium
WD   Working Draft (second stage in developing an ISO or IEC standard)
WG   Working Group or Work Group
WGM  Working Group Meeting
WHO  World Health Organization
WI   Work Item
WTO  World Trade Organisation
XDS  (IHE’s) cross enterprise Data Sharing protocol
XML  Extensible Markup Language