IT-014 Health Informatics Committee

Executive Summary Report

ISO/TC 215 Meeting – Chicago, USA

18- 21 October 2011

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Rapporteur: Michael Steine
Head author: Richard Dixon Hughes
Collated by: Standards Australia

With input from Australian Delegation and other employer funded Australians at the meeting:

- *Richard Dixon Hughes (Head of Delegation)*
- *Heather Grain (Delegate)*
- *David Rowlands (Delegate)*
- *David Rowed (Delegate)*
- *Heather Leslie (Delegate)*
- *Michael Steine (Delegate)*
- *Evelyn Hovenga (Delegate)*
- *Janette Gogler (Delegate)*
- *Naomi Ryan (WG8 Secretariat)*

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 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 e-health 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.

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 TC215 (Health Informatics) include:

- Monitoring and influencing ISO TC215'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 TC215 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 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.

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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.

MEETING AGENDA

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

Welcome to Chicago members of ISO/TC 215 Health Informatics- Working Group meeting and Plenary | 18 - 21 OCTOBER 2011

Chicago, Illinois USA | Holiday Inn Merchandise Mart

TUESDAY 18 OCTOBER 2011

0800 - 1700: Registration 14th Floor Foyer

0830 - 900: Tea / Coffee Break

0900 - 1500: Joint Initiative Council (JIC) Meeting | Sauganash Room | Open to all attendees

1200 - 1300: JIC Group lunch at Holiday Inn restaurant - purchase own lunch under special provided menu

1530 - 1600: Tea / Coffee Break

1600 - 1800: Joint Initiative Council (JIC) OPEN Forum | Sauganash Room | Open to all attendees

WEDNESDAY 19 OCTOBER 2011

0800 - 1700: Registration | 14th Floor Foyer

0830 - 0900: Opening Plenary | Room: Sauganash East

WG 1 & 8 Times	TC/215 - WG 1 & 8	TC/215 - WG2	TC/215-WG -3	TC/215-WG-4	WG6 Not Meeting	WG 7 Not Meeting	Task Forces
	SAUGANASH EAST	WESTERN STAGE	STEAMBOAT	MERCHANT			AMERICAN HOUSE
Q1 0915 - 1030	•Chair: Stephen Kay • Welcome, Introductions & Roll Call • Agenda Review • Other Business • Published / In Publication Standards • DTR 13054, Standards Knowledge Management – Results of DTR Ballot & Disposition of Comments	• Welcome, Introductions & roll call • Agenda review & adoption • Review minutes of last meeting • Report of the WG 2 (acting) Secretariat • Report of Work Program Activities • CDISC-BRIDG Model Ballot Status • Clinical Trials Registration and Registry (CTR&R) NWIP review	• Welcome and roll-call • Review agenda • Review minutes of last meeting • Note any other business •prEN ISO/DIS 13119 – Clinical knowledge resources – Metadata: •prEN ISO/DIS 13120: Syntax to represent the content of health care classification systems	• Welcome - Agenda • 21091 - Directory services ballot results • 17090-1, -2, -3 PKI comment resolution	TC/215 WG6 NOT MEETING	TC/215 WG7 NOT MEETING	Q1 1030 - 1215: Traditional Medicine Task Force
	1030 - 1045: Tea / Coffee Break						
Q2 1045 - 1215	Chair: Marion Lyver • ISO TR 14639 Part 1 – Review of DTR Ballot results and Disposition of Comments Part 2 – Work completed to date; review of gaps and call for authors.		• ISO/NP TR 12310: Principles and guidelines for the measurement of conformance… (Review revised draft TR) • ISO/NP 12975: Principles and guidelines for the maintenance of terminological systems: • Structure and maintenance of the health informatics glossary:	• Possible NWIP on Patient consent • NWIP TR on standards for safe health software (jointly with WG1 & WG8)			
	1215 - 1315: Lunch [Meal ticket] Eat in WG Rooms for Working Sessions						
	1215 - 1315: LUNCH - Meal Ticket - Operations & Harmonization Task Fore Meeting: Room: American House						
Q3 - 1315 - 1500	Chair: Stephen Kay ISO 13972 Quality requirements and methodology for detailed clinical models (1 &2) • Required meta information on DCM concept level (authorship, versioning etc.) • Required DCM content specification (purpose, evidence, references, interpretations etc.)	• Genomics - Pedigree Topic ISO 13449 • HL7 V3 Reference Information Model - Maintenance Release Process	• prEN ISO/DIS 1828: FDIS • Health informatics: Principles of mapping between terminological systems: Issued for DTR ballot • ISO/CD 18104: Proposal to defer • ISO/DTR 16278: DTR ballot • Health informatics - Categorical structure of terminological systems for human anatomy: NWIP • ISO/NP 13581: Guidance for maintenance of object identifiers • ISO/NP 13582: Communication model and XML interface specification for OID registries ISO/NP: Terminology constraints for coded data elements	14441 Security & privacy requirements of EHR systems for use in conformity assessment (Parts 1 & 2)			Q3: 1315 - 1500: xSDO [formally AG] Meeting
	1500 - 1515: Tea - Coffee Break						
Q4 - 1515 - 1600	**WGs 1, 3, 4 & 8: Joint session** Chair: WG4, Lori Fourquet • TR Guidance on Standards for Enabling Safety in Health Software	**WG 1,3, 4 & 8: Joint session [In Sauganash]** • TR Guidance on Standards for Enabling Safety in Health Software • Work Item Status IHE Use Cases and Integration profiles work • Document Registry Federation TR 13128 • Provisions for Health Applications on Mobile/Smart Devices	**WG 1,3, 4 & 8: Joint session** [In Sauganash] • TR Guidance on Standards for Enabling Safety in Health Software	**WG 1,3, 4 & 8: Joint session** [In Sauganash] Chair: WG4, Lori Fourquet • TR Guidance on Standards for Enabling Safety in Health Software			
Q4 1600 - 1700	Chair: Marion Lyver •ISO 13972 Quality requirements and methodology detailed clinical models		Feedback from Traditional Medicine Task Force	• Possible NWIP on Patient consent • NWIP TR on standards for safe health software (jointly with WG1 & WG8)			
	1730 - 2000: Executive Council Meeting - Working Dinner - Invitation Only (HOD's - Convener's - Vice Convener's) - Room: Wolfe Point						

	THURSDAY 20 OCTOBER 2011						
	TC/215 - WG 1 & 8	TC/215 - WG2	TC/215-WG -3	TC/215-WG-4	WG6 Not Meeting	WG 7 Not Meeting	Task Force / Ad Hoc
	SAUGANASH EAST	WESTERN STAGE	STEAMBOAT	MERCHANT			AMERICAN HOUSE
Q1 0900 - 1030	Chair: Stephen Kay • ISO 13972 Quality requirements and methodology - detailed clinical models (1 &2) • Organisation of the Pt 2 document / review part 1 and what needs to go into part 2.	• 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	• Further discussions with Traditional Medicine Task Force	• 17090 NWIP Part 4: digital signature • 16864 Data protection in trans-border flows of personal health information			
1000 - 1030	**WGs 1, 3 & 8 Joint Session** Chair: WG3, Heather Grain • Decision support and alerts		**WGs 1, 3, 8 joint session** • Decision support and alerts [Sauganash]				
	1030-1045: Tea - Coffee Break						
Q2 1045 - 1115	**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	•Terminology Binding Rules NWIP Presentation and Discussion	**Joint session with WGs 1, 3, 8:** • ISO/CD 13940 – System of concepts to support continuity of care – Status, walk-through of website - Via WebEx	• Health Cards • WD 21549-7 Medication – next steps • Review ballot results of 21549-2,-3,-4 and 20301			
Q2 Continued 1045 - 1215	• ISO DIS 16527 PHR system functional model – status report • ISO DIS 10781-r2 – status report		• Revision of ISO/TS 17117-1 – Terminological resources: Part 1 – Characteristics: • ISO/NP 16277-1 – Structure of representation of clinical findings in traditional medicine – Part 1: Traditional East Asian medicine				
	1215 - 1315: Sit down lunch [Meal Ticket] | SAUGANASH WEST Room						
Q3 1315 - 1430	Chairs: Marion Lyver & Co-Chair xSDO Advisory Group: Open to all WGs members who have an interest & wish to attend • PHTF and Joint Initiative for Standards Access and Participation in Low Income Countries • GS1 identification work via JIC	• WADO-Web Services Web Access to DICOM persistent Objects by means of Web Services ISO 12974 Web Access Reference Manifest IS 10159	• ISO 16843 – Health informatics: Categorical structures for the representation of acupuncture: - Part 1: Acupuncture points - Part 2: Needling - Part 3: Channels • New Work Item proposals - TM-TF • Review resolutions to mini plenary • Other business & future meeting dates	• 16114 Security aspects of EHR migration • 22600 PMAC update	TC/215 WG6 NOT MEETING	TC/215 WG7 NOT MEETING	**Q3: 1315 - 1500: xSDO [formally AG] Meeting**
	1500 - 1515: Tea & Coffee Break						
Q4 1515- 1700	Chair: WG8, Marion Lyver • 16555 Framework for National Health Information Systems -Results of NWIP ballot and disposition of comments Motion for DTS ballot	WG2 Closing Plenary		• 27799 ISM in health using ISO/IEC 27002 - SR ballot review & revision strategy			
Note: All WGs must provide Resolution drafts to the Secretariat staff by 1530 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							
1715 - 1815	**Delegation Meetings to discuss Resolutions: Rooms to be assigned.**						
	Social Activity - Cocktail Reception						
	FRIDAY 21 OCTOBER 2011						
	800 - 1700: Registration 14th Floor Foyer						
	TC/215 - WG 1 & 8	WG 2 concluded on Thursday	WG 3 concluded on Thursday	TC/215-WG-4			Task Forces
	SAUGANASH EAST	WESTERN STAGE	STEAMBOAT	MERCHANT			AMERICAN HOUSE
-	**WG1 and WG8 Final discussions**			**WG 4 Final discussions**			
	1100 - 1215: Closing Plenary | Sauganash East						
	1215 - 1300: Buffet - Working Lunch Buffet | Room: Sauganash West						
-	**1300 - 1500: Closing Plenary | Room: Sauganash East**						

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.

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
JIC Open Forum	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. **Action: Australian delegates, be encouraged to attend the now-open JIC meetings.**	**Standards Australia**
JIC **All WGs** **Meeting Planning**	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. **Action: 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.**	**DoHA** **IT14**
All WG's **Getting access to working documents, presentations, past minutes and emails**	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. **Action: 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**	**ISO Secretariat** **SA (at delegate pre-WG meetings)**
WG1, 3 & 8 **System of concepts to support continuity of care (ContSys)** **JIC**	Contsys 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.	**IT-014** **NEHTA** **HL7 Delegates** **Jurisdictions**

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
	ContSys was originally a European (CEN) standard, is used in various European contexts including the UK NHS and is presently being upgraded to become an ISO international standard. ContSys has not had significant exposure in Australia nor at HL7, where Australia has attempted to progress corresponding requirements. 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 there would be considerable benefit in greater alignment between HL7 DAMs DCMs as implemented in Australia and ContSys. 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. **Action: HL7 WGM delegates to continue encouraging HL7 (and its Patient Care WG) to participate to participate in development of ContSys through the HL7 JIC representation.** **Action: 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.** **Action: 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.**	
WG1, 3, 4, 8 **Standards enabling safety in healthcare software**	*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 most 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). **Action: 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.**	**IT-014** **DoHA**

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
WG1 **ISO 13972 Quality requirements and methodology for detailed clinical models (DCMs)** **Parts 1 and 2**	Several sessions were dedicated to ISO 13972 on quality requirements and methodologies in relation to DCMs. The work has been contentious with Australia being among the countries that had voted negatively in a previous ballot (due to a failure 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 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.**	**IT-014-09**
WG1 **ISO 13972 Quality requirements and methodology for DCMs** **Part 3**	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 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**	**IT-014-09** **NEHTA**
WG1 **ISO 13972 bindings to concept codes**	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.**	**IT-014-09**
WG1 **Diagram in ISO 13972 Part 2**	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.**	**IT-014** **Standards Australia**
JIC **CDISC** **Use of standardised data in clinical research** **WG2**	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.	**DOHA** **NHMRC** **IT-014**

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
	In particular, he suggested that a range of CDISC Therapeutic Area Data Standards may be of interest to TC215 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 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. 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 or contribute to it. 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. 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. **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. TC215 agreed at its last meeting in May 2011 that the draft should proceed to publication. The edited final version was submitted to the former TC secretariat but had not been passed on to either ISO Central Secretariat for final publication or to the new TC secretariat by the time of the meeting. 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 TC215 at this meeting. **Action: None required from IT-014. Standards Australia to note.**	**Standards Australia**

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
WG2 **ISO/TS 13131 Quality Criteria for Services and Systems in Telehealth**	This Work Item 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. There has been much debate about use of the terms telemedicine and telehealth. Within TC 215 it has been agreed that the term telehealth is an overarching term and telemedicine is a subset of telehealth. The situation is complicated by various national regulators having their own definitions linked to funding programs and a desire for emerging international standards to support their particular viewpoint. By the last TC215 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.**	**IT-014-12**
WG4 **Integrated framework for tele-biometric data protection in e-Health 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**	**IT-014-12**
WG2 **NWIP: 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) 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 TC215 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.	**IT-014-06** **IHE Australia** **HL7 Australia**

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
	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. **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.**	
WG2 **HL7 RIM :** **Revision of ISO 27131**	In 2005, ISO TC 215 approved ISO 21731, "Health informatics: — HL7 version 3 — Reference information model - Release 1". Subsequently, HL7 has implemented 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 within weeks. Release 4 formally relates to ISO data types as well as underpinning or mapping to multiple ISO standards. The ISO standard is not synchronised to the HL7 RIM releases. The RIM forms the basis of CDA which is the subject of IGs for use in Australian standards at IT-014-06-06 and NEHTA. The critical issue with this item 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. **Action: 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**	**IT-014** **IT-014-06-06** **NEHTA**
WG2 **IS13449 Clinical Genomics - Pedigree Project**	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 TC215 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 / TC215 Secretariat will follow up and facilitate this item proceeding to publication as previously intended. **Action: None required from IT-014. Standards Australia to note.**	**Standards Australia**
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. The work item recently passed NP ballot as a new work item and, at this meeting, comments provided during the NP ballot were disposed. Further development of the draft TR will proceed for consideration at the next meeting of WG2. 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.	**Standards Australia** **MSIA** **HL7 Australia** **HL7 WG Delegations** **IHE Australia** **DoHA and RACGP**

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
	This recognises a whole new infrastructure 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. 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 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. **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.**	
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 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. 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 including a form of Managing Agency with 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**

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
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 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. It was resolved at the last TC215 meeting in May 2011 that the ISO/TC215 Secretariat should circulate an NP ballot of "Health informatics – Clinical Trials – Registration and Reporting" for approval as a new work item targeting an International Standard. Unfortunately, this did not happen but will now be pursued. This item has been through numerous HL7 and CDISC ballots. Accordingly, a fast track process will be sought. **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**
WG2 **Web Access to DICOM persistent Objects by means of Web Services** **ISO 12974 Supplement 148 - WADO**	Web access to DICOM imaging objects ("WADO"). This work proposes that the original I*SO 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). (Details at: ftp://medical.nema.org/medical/dicom/final/sup148_ft.pdf) In developing the supplement, a couple of changes were made to the original WADO to make it work with web services. A joint TC215/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 is taking place in the Australian health community with GP access to 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. **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**	**IT-014-06** **NEHTA**

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
WG3 **Decision Support and Alerts** **TR 14668** **Guidelines for the principles and desirable features of clinical decision support systems.**	This is based on the Australian IT 14 work and is in three parts: 1.System foundations, 2.Technical foundations, and 3.Alert system requirements There is a need for agreement on defintions of alerts and trigger event (which had been considered to be in-system application events). The issue with the latter being whether external to system vs internal to system. The trigger event in HL7 messaging is an absolute core concept and refers to a real world event external to systems but which is required to align to message reflection of workflow. Internal system events might be appropriately considered as state transitions in the system. **Action: 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 cognisant of existing and HL7 products and gaps, and take the work through HL7 and ISO ultimately targeting JIC level.** **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.**	**IT-014** **HL7 Delegates attending CDS**
WG3 **Expressing terminology constraints on coded data elements** **(with WG2)**	This work item (formerly known as "terminology binding" is based on previous HL7 work coming into ISO that describes how to apply terminology to particular data elements, for example in information models, data dictionaries, etc. It 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 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. **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.**	**IT-014-02** **IT-014-06** **IT-014-09** **Collaborating with:** **NEHTA** **HL7 Australia** **IHE Australia**
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** **HL7** **NEHTA** **IT-014-02**

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to 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 and provide comment and named expert(s)in response to**	**IT-014 to**
WG3 & TMTF **Semantic network framework & coding of TCM Language systems**	Traditional Chinese medicine (TCM) is inadequately supported by existing language systems and semantic networks for the purpose of facilitating the 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 TMTF resolved to agree the scope and content of a proposed technical specification (TS) on *Semantic network framework and coding of Traditional Chinese Medicine language system*, and to recommend this progressing to NP ballot as a new work item. This was agreed by TC 215. **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**
TMTF & WG3 **TCM Literature Metadata** **&** **TCM equivalent of UMLS**	*Traditional Chinese Medicine Literature Metadata*. This project would define the metadata necessary to define knowledge and publications related to TCM literature. *Semantic network framework and coding of literature of Chinese medicine language system*. This work underpins the development of a 'version of UMLS' that represents traditional Chinese medicine. Working Group members believed that this work underpins 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 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**
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** **IT-014-04**
WG4 **ISO 17090 Parts 1,2,3 Public Key Infrastructure**	AS 17090 parts 1-3 were published in 2003 by Standards Australia and will need to be revised to align with this planned 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**

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
WG4 **NWIP ISO 17090 Part 4 Digital Signatures**	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* on current work**	**NEHTA** **IT-014-06** **IT-014-04**
WG4 **New work on requirements for consent**	There are a number of concerns about the scope of the proposed NWIP 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. **Action: IT-014 to continue involvement and monitoring of this NWIP**	**IT-014**
WG4 **EN/ISO 16864 Data protection in trans-border flows of personal health information**	Joint ISO/European work on EN/ISO 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 **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**
WG4 **DTS 22600 Privilege Management and Access Control**	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 Security: **DTS 14441 Security & privacy requirements of EHR systems**	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**
WG8 **DTR 13054, Standards Knowledge Management**	DTR 13054 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 NHSIC. 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.	**IT-014** **NEHTA** **IT-014-02**

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
	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 NHTA 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**	
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 communic-ation**	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**

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
WG 8 **Capacity-based eHealth architecture roadmap – Part 2: architectural components & maturity model**	Many contributors/editors have been involved in this document and more detailed contributions now exist for about half the sectons. This TR will complement and support the 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. Completion of draft is now expected by the end of the year (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 **NWIP 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**

FUNDING SOURCE SUMMARY AND ATTENDANCE

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.

Funding Source	Number	Change from Previous Meeting
Full funding by employer: Private	0	-1
Full funding by employer: States/Territories or National Initiatives (NEHTA)	0	0
Funding Assistance – DOHA through Standards Australia contract	9	+2
Total:	**9**	**+1**

The Australian delegation comprised:

- *Richard Dixon Hughes (Head of Delegation)*
- *Heather Grain (Delegate)*
- *David Rowlands (Delegate)*
- *David Rowed (Delegate)*
- *Heather Leslie (Delegate)*
- *Michael Steine (Delegate)*
- *Evelyn Hovenga (Delegate)*
- *Janette Gogler (Delegate)*
- *Naomi Ryan (WG8 Secretariat)*

AUSTRALIAN POSITIONS HELD BY DELEGATES

The DOHA funded delegates were selected through an independent panel process jointly with NEHTA, DOHA, HL7 Australia and Standards Australia. The positions of these delegates (including leadership positions) are listed below.

Attendee	Position (held at the meeting)	Funding Source	Working Group or Committee
Richard Dixon Hughes	Head of Delegation	Standards Australia via the DoHA Funding Agreement	TC/215
Richard Dixon Hughes	Executive Council member	Standards Australia via the DoHA Funding Agreement	JIC Harmonisation,
Richard Dixon Hughes	(as HL7 alternate)	Standards Australia via the DoHA Funding Agreement	JIC Executive
Richard Dixon Hughes	Member & lead	Standards Australia via the DoHA Funding Agreement	TC 215 Organization Task Force
Heather Grain	Convener (elected to May 2013)	Standards Australia via the DoHA Funding Agreement	WG3 Semantic Content
Heather Grain	Member	Standards Australia via the DoHA Funding Agreement	TC 215 Organization Task Force
Heather Grain	Member	Standards Australia via the DoHA Funding Agreement	Operations & Harmonization Committee
Naomi Ryan	Secretariat	Standards Australia via the DoHA Funding Agreement	WG8 Business Requirements for EHR (and WG1 Data Structure at this meeting)
Naomi Ryan	Member	Standards Australia via the DoHA Funding Agreement	Operations & Harmonization Committee

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 Comformance Framework
EFMI	European Federation of Medical Informatics
EHR	Electronic Health Record
EHRS or 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
IT-014	Standards Australia Committee IT-014 (Health Informatics)

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 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 [under the JI, unless otherwise specified]
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&MRC	National Health and Medical Research Council
NHIN	(US) National Health Information Network
NHS	(UK) National Health Service
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

NWIP	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
PHR	Personal Health Record
PHTF	Public Health Task Force
PIM	Platform Independent Model
PIP	Practice Incentive Payment
PIR	Post Implementation Review
PKI	Public Key Infrastructure
PM	Project Manager
PMBOK	Project Management Body of Knowledge
PMS	Practice Management System
PMTL	Project Management Team Leader
PoC	Point-of-Care

PSM	Platform Specific Model
RACGP	Royal Australian College of General Practice
RCPA	Royal College of Pathologists Australia
RHIO	(US) Regional Health Information Organisation
RIMBAA	RIM Based Application Architecture
RIM	Reference Information Model
RIS	Radiology Information Systems
RLUS	Resource Locate Update Service (HSSP)
RM-ODP	Reference Model of Open Distributed Processing
SA	Standards Australia
SAIF	Services Aware Interoperability Framework
SC	Subcommittee
SDO	Standards Development Organisation
SIG	Special Interest Group
SKMT	Standards Knowledge Management Tool
SLA	Service Level Agreement
SME	Subject Matter Experts
SMTP	Simple Mail Transfer Protocol
SNOMED	Systematised Nomenclature of Medicine
SOA	Service Oriented Architecture
SOAP	Simple Object Access Protocol
TC	Technical Committee
TCM	Traditional Chinese Medicine
TCP/IP	Transmission Control Protocol/Internet Protocol
TEAM	Traditional East Asian Medicine – This term, though inadequate is used to represent Traditional Chinese Medicine, Traditional Korean Medicine, Traditional Japanese Medicine.
TF	Task Force
TM	Traditional Medicine
TOGAF	The Open Group Architecture Framework

TR	Technical Report (an informative ISO or IEC standards publication)
TS	Technical Specification (a normative standards publication having a lower level of consensus than a full international standard)
UCUM	Unified Code for Units of Measure [Regenstrief Institute]
UML	Unified Modelling Language
UN	United Nations
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