

IT-014 Health Informatics Committee

Final Report

ISO Meeting

Rotterdam, Netherlands, October 2010



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Collated by: Standards Australia

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- *Evelyn Hovenga (Delegate)*
- *Heather Leslie (Delegate)*
- *Anthony Maeder (Delegate)*
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- *Andrew Caswell (WG8 Secretariat)*

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1 INTRODUCTION

ISO (International Organization for Standardization) is the world's largest developer of standards. ISO is constituted as a network of the national standards institutes of 148 countries, on the basis of one member per country, with a Central Secretariat in Geneva, Switzerland.

Although ISO's principal activity is the development of technical standards, ISO standards also have important economic and social repercussions.

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 organizational 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 (coordinating working group activity, secretariat processes and TC 215 work program).

In May 2010, the TC 215 Executive Council also formed a Business Planning and Reorganization Task Force to review and report back in one year on TC 215's strategic direction, its business plan and its organisation structure – with Richard Dixon Hughes and Heather Grain both being active members.

In addition, TC 215 hosted a face-to-face meeting of the Joint Initiative Council (JIC) and the JIC Harmonization Open Forum at which collaborative projects potentially involving several JIC members are discussed, approved and tracked. The current members of the JIC are: ISO/TC 215, CEN/TC 251, HL7 International, CDISC, IHTSDO and GS1.

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 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.

2 MEETING ORGANISATION

ISO/TC 215 holds two full international meetings per year. The first (in April/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 seven 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 Joint Working Group Meeting for 2010 was hosted by NEN, the ISO national member body for The Netherlands and covered four days from 10 to 13 October in accordance with the agenda below. A full day of TC 215 leadership and information-sharing meetings was held at Novotel Rotterdam, Brainpark Hotel on the Sunday with the following three days taking place in the Congress Centre of Erasmus University, located within a few minutes walk from the hotel.

The meeting was attended by between 150 and 200 delegates from 18 participating member countries (compared with 16 at the May 2010 meeting in Rio de Janeiro, Brazil) and included representatives of liaison organisations including TC 249 TCM, IHTSDO, GS1, WHO, ICH, JTC1, CDISC and IEEE.

Being held in Europe most sessions were held jointly with the European CEN/TC 251 Health Informatics committee and its four working groups.

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 number of concurrent sessions and the unavailability of experts in some of the TC 215 subject areas make it difficult for a small delegation to effectively follow the issues and to influence change in all of the active areas.

Agenda

The agenda for the four days was as follows:

	A	B	C	D	E	F	G	H	I	K	
1											
2			ISO/TC 215 & CEN/TC 251 Health Informatics								
3			10-13 October 2010								
4			Rotterdam, Netherlands								
5	Date	Time	Sunday Schedule is in NOVOTEL Rotterdam Brainpark Hotel								
6	Sun	0830-1100	Executive Council Meeting (HOD's - Convener's - Vice Convener's) (includes lunch) Room: Rotterdam								
7		1130-1330	Formatting Class by ISO/CS for WG leadership Room: Rotterdam								
8	10-okt	1400-1600	Joint Initiative Open Forum, Open to all JWG attendees								
9		1630-1830	Joint Initiative Open Forum session on software as Medical Devices--Open to all JWG attendees--Room: Rotterdam								
10											
11	Date	Time	Monday-Tuesday-Wednesday Schedule at Erasmus University								
12		0900-1000	MINI-OPEN PLENARY (Forum room)								
13		1000-1015	Coffee Break								
14	Mon	WG List	215-WG-1-8/251-WG-1	215- WG2	215-WG-3/251-WG-2	215-WG-4/251-WG-3	215-WG6	215-WG-7/251-WG-4	Task Forces	Additional RM	
15		ROOM	FORUM (58)	Lund (29)	Heidelberg (31)	Rochester (32)	Santander (32)	Aberdeen (27)	Auckland		
16		1016-1215	Welcome-Agenda Proposed New Ways of Working Review Published Standards/Er Framework for Nat'l Health Enterprise Architecture	Welcome-Agenda Review CDISC-BRIDG Status Clinical Trials Reg NWIP review	Welcome-Agenda Review minutes Update 12300 Revision of 17117 18104 Revision	Welcome-Agenda Review Patient Safety and Quality Task Force	Welcome-Agenda Review Update of 10886 Ballot results TR26267	IEEE 11073 meeting report IEEE 11073 PHD meeting report	DCM Meeting Only	Invite	
17	11-okt	1216 - 1316	LUNCH (O&H meeting)								
18		1316 - 1600	Joint with WG 8 Genero Model for Dose Syntax IDMP Update 14635 162 KN Mgmt HI 13054 14186 BRIDG	Genomic - Pedigree Topo IS 13449	OID discussion 13581 and 13682 13118 Metadata 17116 SR discussion	DT8 14441 Security & privacy req. of EHR for use in conformity assessment	Joint session with WG 1 Genero model for dose syntax Update on IDMP	Report of European 'eHealth' standards Review of work plan (215/WG7 & 251/WGIV)	Traditional Medicine Task Force	Re-Organization Task Force Meeting Jeremy Thorp, chair	
19		1600 - 1616	Coffee Break								
20		1616 - 1700	Use Case Template for HI projects 16223 Standards Convergence 13872 DCM	Work Item Status IHE Use Cases and integration profiles work	TR for Glossary Database 12310/12975 Term Sys 16278 H-A term sys	TR 18114 Security aspects of EHR migration	ISO/TR 14872	Continuation of topic	JIC Harm session as agenda		
21		1700-1800							RA meeting with Atsuko	JIC Harm session as agenda	
22											
23	Date	Time	Tuesday Schedule								
24		WG List	215-WG-1-8/251-WG-1	WG2	215-WG-3/251-WG-2	215-WG-4/251-WG-3	WG6	215-WG-7/251-WG-4	Task Forces		
25		ROOM	FORUM (58)	Lund (29)	Heidelberg (31)	Rochester (32)	Santander (32)	Aberdeen (27)	Auckland		
26	12-okt	0800-1030	Begin at 0830 13808 /18308 EHR 13872 DCM 14292 PHR 10781 R2	Telehealth T8 13131	TMTF feedback	TF Health Cards 26238 Clarick--SR	IC3R #27963-1 2nd DIS comments review	ISO/IEC JWG7 80001-x Update (network risk management) 26238 Clarick--SR	Patient ID Meeting		
27		1030-1046	Coffee Break								
28		1046-1215	NWIP PHR Sys FM 14286 Data Purposes Health Summary Req Bus Req	WADO-Web Services IS12874	18277-1 Clinical findings in TM prEN ISO 1828 13120 Syn medical classification 13940-1 &2 Continuity of Care	27788 EHR Audit trails 22867 Data protection in trans-border flow	IC3R #27963-2 2nd DIS comments review	DCM update MFER NWIPs IEEE 11073 draft standards rw	JIC Harm session as agenda		
29		1216 - 1316	LUNCH ContSys1 and 2 coordination meeting								
30		1316 - 1600	T8 21081 Directory Services Enablers of CDSS	Document Registry Federation TR 13128 Reference Model/Terminology Binding Rules Discussion IS2190 Data Types	Joint meeting WGs 1-3-8 CDSS-Alerts and user interface	CEN/TC251/WG III Formal meeting	Formal WG6 meeting	IHE ICE-PAC Rapid Device config Update on FEF (EN14271) Ballot review Standalone SW & MDO	JIC Executive Session		
31		1600 - 1616	Coffee Break								
32		1616 - 1700	Continuity of Care & Resolutions	New Business, Review of Resolutions and WG closing Plenary	Review Resolutions Consider other business Dates of future meetings.	ISO/TC215/WG 4 Formal meeting	Formal WG6 meeting Closing and WG resolution development Due at 1030	Educational/Primer materials Resolutions	JIC Executive Session		
33		1700-1800	Canadian Delegation Meeting	Australia Delegation Meeting	Japan Delegation Meeting	Brazil Delegation meeting	Netherlands Delegation meeting	US Delegation Meeting	UK Delegation Meeting		
34		1800-2000	Rotterdam City Hall Social Event -								
35											
36											
37											

	A	B	C	D	E	F	G	H	I	K	
38	Date	Time	Wednesday Schedule								
39	Date	Time									
40		0730 - 0845	216-WG-1-8/261-WG-1	WG2	216-WG-3/261-WG-2	216-WG-4/261-WG-3	WG6	216-WG-7/261-WG-4	Task Forces		
41	Wed	0845 - 0900	FORUM (58)	Lund (29)	Heidelberg (31)	Rochester (32)	Sanfander (33)	Aberdeen (27)	Auckland		
42	13-oct	0900 - 1030	Closing and WG resolution development Due at 1030	Callope Meeting Thorp Jeremy	Closing and WG resolution development Due at 1030	Closing and WG resolution development Due at 1030	OPEN	Closing and WG resolution development Due at 1030	Open		
43		1030-1045	Coffee Break								
44		1045 - 1215		Callope Meeting Thorp Jeremy			OPEN	Closing and non-resolution topics	JIC Harm session as agenda		
45		1045 - 1215	Resolutions review/collated by the TC secretariat								
46		1215 - 1315	Lunch and Resolution Distribution to all HOD's at 1215								
47		1315 - 1500	Mini-Plenary 1315-1700 Room: FORUM							Mini-Plenary cannot begin until all resolutions are done, checked and accepted.	
48		1500 - 1515	Coffee Break								
49		1515 - 1700	Mini-Plenary 1315-1700								
50											

3 MATTERS FOR AUSTRALIAN ACTION

The principal issues / actions and recommendations identified by the Australian delegation at the October 2010 ISO TC 215 Meeting in Rotterdam may be summarised as follows:

Topic	Issue/Action and Recommendations for Australia	Alignment to IT014 Structure
Executive Council Meeting	<p>Ongoing maintenance of evolving standards and standardized code sets are issues facing some TC 215 groups. ISO rules provide two types of structures to assist in this area:</p> <ul style="list-style-type: none"> Maintenance Agency – maintains normative elements that require regular maintenance in a standard - such as code system content. Registration Agency which registers items such as OIDs in a database. <p>Maintenance agencies must be an ISO national member body or a standardization organisation that performs the function on behalf of a NMB.</p> <p>A Maintenance Agency may be required for some of the pharmaceutical identification standards.</p> <p style="color: orange;">Action: IT-014 needs to understand and look to work within any RA/MA frameworks established by TC 215</p>	IT-014, its subcommittees and Standards Australia
Executive Council Meeting	<p>Management of definitions and terminology in standards – availability of both the Health Informatics SKMT definitions and standards databases and the ISO Concept Data Base (CDB).</p> <p style="color: orange;">Action: IT14 to consider whether it should adopt the same procedure as TC 215 to achieve definitional consistency – SKMT first, then ISO concept database</p>	

<p>Business Planning & Organization Task Force</p>	<p>The task force reported on its work and presented its Interim Report designed to:</p> <ul style="list-style-type: none"> • provide an agreed description of scope and objectives for TC 215 • identify potential organisational models • propose a process for the appraisal of these models, including appropriate assessment criteria <p>Action: Richard Dixon Hughes and Heather Grain to keep IT-014 informed of the activities of the TC 215 business planning and reorganization task force and the alternative structures for TC 215.</p> <p>Action: IT-014 needs to ensure that the business plan and on-going organisation will address Australian needs effectively.</p>	<p>IT-014, Richard Dixon Hughes & Heather Grain (as TF members)</p>
<p>Formatting Class</p>	<p>Instructions from the ISO Central Secretariat on the preparation and format of standards documents were relayed to WG conveners, vice conveners and secretariats. This included advice on the drafting of titles, provisions, scope, conformance criteria, normative references self referencing, clauses, subclauses with and without titles, paragraphs and hanging paragraphs, notes, examples and lists.</p> <p>ISO have implemented their concept database which is available at www.cdb.iso.org.</p> <p>Existing tools and information for drafting of standards (including the SKMT glossary management tool) should be more widely used. Groups seeking terms and definitions for TC215 will first seek existing definitions from the SKMT, then check the ISO tool:</p> <p>IT-014 and Standards Australia will need to consider whether we should adopt the same procedure – SKMT first, then ISO concept database.</p>	<p>IT-014, its subcommittees and Standards Australia editorial staff</p>
<p>Joint Initiative Council Harmonisation</p>	<p>In order to be more open, inclusive and informative, the JIC now has three types of meetings</p> <ul style="list-style-type: none"> • Open Forum - where issues are openly discussed and open to the whole community • Harmonisation Track – where specific issues of harmonisation between the members are discussed and open to the whole community • Council Meeting - which is the only closed meeting. <p>A new web site for the Joint Initiative Council (holding a registry of all JIC projects, Inventory of policies and record of all meetings and agendas has been established and can be found at: www.jointinitiativecouncil.org. The website replaces the JWG/JIC website formerly managed by Standards Australia on behalf of ISO/TC 215/WG9.</p> <p>IT-014 and TC 215 Delegates will need to become more familiar with the working of the JIC and consider how best to utilise its facilities.</p>	<p>IT-014 and ISO TC 215 Delegation Members</p>

<p>Working Group 1</p>	<p>WG1 and WG8 held all of their working sessions jointly – where most of the document progression is detailed. The following document was at its final stages prior to publication [and was subsequently published on 26 November:</p> <ul style="list-style-type: none"> • <i>ISO 21667 Health indicators conceptual framework.</i> <p>There is considerable interest in the document at national level in Australia.</p> <p>Australia will now need to consider this standard for local adoption.</p>	<p>IT-014-09</p>
<p>Detailed Clinical Models (DCM)</p>	<p>Australia is a significant contributor to this work as well as being a significant critic of some aspects and has provided much of the input and expertise, while having voted against the work (as proposed) – on the grounds that it was not sufficiently advanced to become the basis of a full International Standard.</p> <p>Action: IT-014-09 to continue oversight of Australian engagement and assisting Australian experts Heather Leslie, Richard Dixon Hughes, Stephen Chu and Evelyn Hovenga to contribute to their respective parts.</p>	<p>IT-014-09</p>
<p>Working Group 2 Communications Topics</p>	<p>This group is working on several joint initiatives including:</p> <ul style="list-style-type: none"> • <i>BRIDG V3.0.2</i> currently out for DIS ballot • NWIP “<i>Clinical Trials Registration & Reporting</i>” • NWIP “<i>HL7 V3 Reference Information Model - Maintenance Release Process</i>” <p>The two foundation TRs on IHE process and profiles (of interest to Australia) had still not progressed but another person was appointed to facilitate their finalization.</p> <p>As much of the WG2 work draws on HL7, IHE, CDISC work or is in areas where Australia has not been active, WG2 engagement has been a lower priority for Australia – except for the area of telehealth; however, closer attention is warranted to ensure joint work is completed.</p>	<p>IT-014 IT-014-06 and sub-groups</p>
<p>Working Group 2 Telehealth</p>	<p>WG2 is also progressing two documents of interest in the area of telehealth:</p> <ul style="list-style-type: none"> • TS “<i>Quality Criteria for Services and Systems in Telehealth</i>” • NWIP for a TR “<i>Provisions for Health Applications on Mobile/Smart Devices</i>” 	<p>IT-014-12</p>
<p>Working Group 3</p>	<p>Work in this group progressed as indicated below:</p> <ul style="list-style-type: none"> • <i>ISO/NP TR12300 Mapping of terminologies to classifications</i> <p>This work is led by Australia and is out to ballot.</p> <ul style="list-style-type: none"> • <i>ISO/TS 17117 Criteria for the categorisation and evaluation of terminological systems</i> <p>This work is a review of the existing TS and targets an IS with the title:</p> <p>Health Informatics - Terminological resources Part 1 – Characteristics Part 2 – Requirements Part 3 – Criteria for evaluation</p>	<p>IT-014-02 have oversight of this project</p> <p>IT-014-02 and NeHTA</p>

	<ul style="list-style-type: none"> • <i>Revision of ISO 18104:2003 Integration of a reference terminology model for nursing</i> Issues discussed related to the need to clarify specific concepts within this work item, as well as the title of the work item. • System of concepts for the continuity of care - ContSys This is a CEN work item in two parts: - Part 1 - Basic concepts - Part 2 - Health care process and workflow. <p>Several IT-014 subcommittees (see next column) are engaged in contributing to and monitoring these projects.</p>	<p>IT-014 (particularly members representing nursing organisations)</p> <p>IT-014-06, IT-014-09 and NeHTA</p>
<p>Working Group 4</p>	<p>The documents below were the focus of the group's attention during the meeting:</p> <ul style="list-style-type: none"> • <i>ISO DIS2 21091, "Health informatics: Directory Services for healthcare providers, subjects of care and other entities"</i> This is of concern to some Australian experts who have implemented systems in this area. Wider discussion warranted. • <i>ISO Publication TS14265, "Classification of Purposes for processing personal health information"</i> • <i>NWIP IS "Health informatics — Data Protection in trans-border flows of personal health information"</i> • <i>ISO Withdraw TS 25238, "Classification of Safety risks from health software"</i> • <i>ISO SYSREV TS 22600 Health informatics -- Privilege management and access control part 3:Implementations</i> <p>The WG also received and discussed a report from the TC 215 delegation to the meeting of the ISO/TMB Privacy Steering Committee (PSC) held in Berlin in the week before the Rotterdam meeting. It appears that ISO is keen to coordinate activities in the area to address broader privacy protection issues in collaboration with privacy commissioners.</p> <p>The WG also dealt with recommendations of the Health Cards TF in relation to the update, renewal and republication of various health card standards.</p> <p>The work of WG4 and associated sub-groups is relevant to Australia as we move forward on privacy and security issues associated with the PCEHR and with identification management in healthcare. Greater local engagement is sought.</p>	<p>IT-014 IT-014-04 and NeHTA</p>

<p>Working Group 6</p>	<p>This group held several joint sessions and only its own projects are reported here. Three projects were progressed towards publication:</p> <ul style="list-style-type: none"> • <i>ISO FDIS 27953-1 "Health informatics – Pharmacovigilance – Individual case safety report [ICSR] – Part 1: The framework for adverse event reporting"</i> • <i>ISO FDIS 27953-2 "Health informatics – Pharmacovigilance – Individual case safety report – Part 2: Human pharmaceutical reporting requirements for ICSR"</i> • <i>ISO DTR 14872 "Health informatics – Requirements for the implementation of the standards for the identification of medicinal products [IDMP] for the exchange of regulated medicinal product information"</i> <p>Two New Work Items Proposals were also generated:</p> <ul style="list-style-type: none"> • <i>NWIP TS "Health informatics – Requirements for international machine-readable coding of medicinal product package identifiers"</i> • <i>NWIP TS "Health informatics – Business requirements for a syntax to exchange structured dose information for medicinal products",</i> <p>Australia does not have a group active on the ICSR and IDMP work and will need to find appropriate experts to assist in determining its support (or otherwise) for these latter two.</p>	<p>IT-014 and NeHTA</p>
<p>Working Group 7</p>	<p>This group is not specifically monitored by Australia. Its final recommendation was to present a Preliminary New Work Items for International Standards on the following IEEE 11073 projects:</p> <ul style="list-style-type: none"> • <i>11073-10419 Health informatics - Personal health device communication- Device specialization - Insulin pump</i> • <i>11073-10420 Health informatics - Personal health device communication - Device specialization - Body composition analyzer</i> • <i>11073-10421 Health informatics - Personal health device communication - Device specialization - Peak expiratory flow monitor (peak flow)</i> • <i>11073-10418 Health informatics - Personal health device communication - Device specialization - INR analyzer</i> • <i>11073-10413 Health informatics - Personal health device communication- Device specialization - Respiration rate</i> • <i>11073-10443 Health informatics - Personal health device communication- Device specialization - Physical activity monitor</i> 	<p>IT-014 generally with input on specific issues via leadership of IT-014-06 IT-014-09 IT-014-12</p>

<p>Working Group 8</p>	<p>The working group had several significant presentations, but three work items were brought forward for progression:</p> <ul style="list-style-type: none"> • DTR 14639 “<i>Capacity-based e-health architecture roadmap – Part 1:Environmental scan</i>” Richard Dixon Hughes and Anthony Maeder have made significant contributions to parts 1 and 2 of DTR 14639. • TR 13054 “<i>Knowledge Management of health information standards</i>” Heather Grain is Australian lead and draws on IT-014-02 expertise to moderate differences. • TR 14292 “<i>Personal health records – definition, scope and context</i>” Relevant to PCEHR and similar information communication involving privacy consent. <p>Australia has significant commitment to WG8 through the secretariat and associated close relationship with WG1. The 3 projects being progressed warrant careful monitoring. TR 13054 is of particular significance to Australia and has potential impact across the whole health informatics space.</p>	<p>IT-014, IT-014-09 and NEHTA</p> <p>Standards Australia as WG8 secretariat</p> <p>IT-014 and IT-014-02 (Heather Grain) on TR 13054 and vocab management</p>
<p>Traditional Medicine Task Force</p>	<p>The task force met separately to WG3 for a half day.</p> <p>Attendance at the meeting of a formal representative and Liaison from the Traditional Medicine TC of ISO from China was welcome and the meeting was constructive. This is an enormous step forward.</p> <p>Two new work items were developed and presented:</p> <ul style="list-style-type: none"> • <i>Categorical structures for representation of acupuncture – Part 1 – Acupuncture points</i> • <i>Categorical structures for representation of acupuncture – Part 2 – Needling</i> <p>Other work in preparation includes</p> <ul style="list-style-type: none"> • <i>Traditional herbal medicine – Part 1 – General Principles</i> • <i>Traditional herbal medicine – Part 2 – Japan</i> • <i>Traditional herbal medicine – Part 3 – Korea</i> <p>IT-014 needs to consider how we gain experts to contribute appropriately to these work items and the priority of this work to Australia.</p>	<p>IT-014</p>

4 AUSTRALIAN PARTICIPATION

4.1 ATTENDANCE DETAILS

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

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	Executive Council JIC Harmonisation, WG8, WG1, (WG4 and WG7)
Heather Grain	Delegate	Standards Australia via the DoHA Funding Agreement	Executive Council WG3 (as convener), JIC Harmonisation and Traditional Medicine Task Force
Evelyn Hovenga	Delegate	Standards Australia via the DoHA Funding Agreement	WG1, WG6 and Traditional Medicine Task Force (WG8)
Heather Leslie	Delegate	Standards Australia via the DoHA Funding Agreement	WG1 (WG8)
Anthony Maeder	Delegate	Standards Australia via the DoHA Funding Agreement	WG4 and JIC Harmonisation
Klaus Veil	Delegate	Standards Australia via the DoHA Funding Agreement	WG2 and JIC Harmonisation (WG7)
Andrew Caswell	Delegate	Standards Australia via the DoHA Funding Agreement	WG8 (Secretariat)

4.2 FUNDING SOURCE SUMMARY

The funding source for these delegates is indicated in the table below.

Funding Source	Number
Full funding by employer: Private	0
Full funding by employer: States/Territories or National Initiatives (NeHTA)	0
Full funding – DOHA through Standards Australia contract	7
Total:	7

The DOHA funded delegates were selected through an independent panel process jointly with NEHTA, DOHA, HL7 Australia and Standards Australia.

4.3 PARTICIPATION LOGISTICS

The overall Australian delegation in Rotterdam was considerably smaller than the 11 we had in the May 2010 meeting (in Rio de Janeiro) because there were no NEHTA representatives as the meeting was not co-located with HL7 on this occasion.

ISO/TC 215 generally has up to eight concurrent streams at its meetings and the actual agenda for each work group tends to vary from that published prior to the meeting, depending on the availability of key contributors, many of whom have commitments to multiple groups.

Given the limited size of the Australian delegation and the expertise and interests of the delegates, the delegation necessarily covers some areas in greater depth than others with the allocation of responsibilities taking into account and the priorities set out in IT-014's current objectives for Australian engagement in international standards development as discussed with DoHA.

Australia continues to struggle to find the specific expertise and resources needed to provide sustained coverage of the following active TC 215 committees

- WG 4 Security, Privacy and Patient Safety,
- WG 6 Pharmacy and Medication Business;
- WG 7 Devices

To some extent, this reflects Australian national priorities and the lack of active IT-014 mirror committees working in these domains. The notable exception is WG 4, which does align with national e-health priorities. The Australian IT-014-04 mirror committee also struggles to elicit the needed levels of involvement, partly because the community of interest in Australia is relatively small and overcommitted. Nevertheless, it is generally accepted that Australia should be more actively involved in the areas of security, privacy and patient safety as they relate to the healthcare sector.

To monitor and plan its involvement, the Australian delegation met on a regular basis to identify emerging issues and the sessions which should be covered - particularly noting those that are relevant to the Standards Australia IT-014 and/or NEHTA work plans.

Attendees from other countries are largely funded to attend by their employer or as consultants to national programs to influence ISO developments, and to return expertise to their own country. This support by Governments and employers does not negate the voluntary nature of much of the work which is done on weekends and evenings, out of work time, but does indicate the value attached to the activities by employers and national programs around the world.

4.4 AUSTRALIAN LEADERSHIP POSITIONS

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

Working Group or Committee	Position	Status	Person
WG 3 – Semantic Content (Terminology)	Convenor	Elected (to May 2013)	Heather Grain
WG 8 - Business Requirements for EHR	Secretariat	Appointed	Standards Australia (IT-014 Snr Project Mgr)
WG 9 – Joint Working Group for SDO Harmonisation	Secretariat	Discontinued due to adoption of new model for JIC consultation.	Standards Australia
Australian Delegation	Head of Delegation	Appointed	Richard Dixon Hughes
TC 215 Business Planning and Reorganization Task Force	Members	Appointed	Richard Dixon Hughes Heather Grain
ISO/IEC JTC 1 Liaison to TC 215	Nominated JTC 1 Liaison Officer	Appointed by JTC 1	Richard Dixon Hughes

5 TC 215 MEMBERSHIP AND ORGANISATION

The current TC 215 “Participating” P-Members and “Observing” O-Members by continent are as follows:

Continent	P-Members	O-Members
Africa	Kenya	South Africa, Zimbabwe
North America	Canada, USA	
South America	Brazil	Argentina, Ecuador
Asia	China, Japan, Korea, Malaysia	Hong Kong, India, Iran, Mongolia, Singapore, Thailand
Europe	Armenia, Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Netherlands, Norway, Russian Federation, Serbia, Slovakia, Spain, Sweden, Turkey, United Kingdom	Bulgaria, Croatia, Cyprus, Hungary, Israel, Poland, Portugal, Romania, Ukraine, Switzerland
Oceania	Australia, New Zealand	
	Total = 29 (15 present)	Total = 20 (1 present)

Participating member countries have voting rights and obligations to host meetings and provide secretarial support to the activities of the TC.

The current Chair of ISO/TC 215 is Dr Christopher Chute, from the Mayo Clinic, USA, who took over on 1 January 2010 from Dr Yun Sik Kwak of Korea (who served in the role for the maximum period of 6 years).

The ISO/TC 215 secretariat also services the **Joint Initiative on Health Informatics Standards Development Organisation Harmonisation** (JI). This initiative is realised through an executive-level **Joint Initiative Council (JIC)** that has the objectives of reducing overlap and inconsistency and promoting economy of effort in the standards development activities of ISO/TC 215, CEN/TC 251, HL7 and other health informatics standards development organisations (SDOs).

Through WG 7, TC 215 also participates in a joint working group with IEC/SC62A and IEEE, constituted as IEC/62A/JWG7. This group is working on controversial new technical standards for “*Application of risk management to information technology (IT) networks incorporating medical devices*”. More details are available at:

http://www.iec.ch/dyn/www/f?p=102:14:0:::FSP_ORG_ID:2471.

Vale: Dr Yun Sik Kwak

It is with great sadness that we learnt of the sudden death of Dr Yun Sik Kwak, immediate past Chair of TC 215, on 24 November 2010 at the age of 74.

Standards Australia Committee IT-014 along with past and present members of Australian delegations to TC 215, extend their condolences to Dr Kwak's friends and family and express their thanks for the many contributions that he made during his life.

In particular, we remember him for pioneering the Health IT Summits which transformed health IT SDO collaboration and for his many contributions in the areas of medical devices, pathology, and the promotion of mutual understanding of traditional Asian and Western allotropic traditions of medicine.

6 TC 215 WORK PROGRAM

As at December 2010, the ISO/TC 215 Health Informatics committee had published some 83 ISO deliverables (i.e. International Standards, Technical Specifications, Technical Reports etc).¹

TC 215 currently has some 108 ISO deliverables on its active work program, distributed among the Working Groups as follows:

WG 1	<i>Data Structure</i>	8 items
WG 2	<i>Data Interchange</i>	14 items
WG 3	<i>Semantic Content</i>	19 items
WG 4	<i>Security, Safety and Privacy</i>	9 items
WG 6	<i>Pharmacy and Medication Business</i>	12 items
WG 7	<i>Devices</i>	34 items
WG 8	<i>Business Requirements for EHRs</i>	8 items
	<i>Electronic Health Cards Task Force</i>	6 items

These include 28 preliminary work items being drafted or under active consideration. The 28 preliminary work items include 20 device interface specifications that are being developed by IEEE but have been identified for fast-track adoption through TC 215/WG 7.

Joint work is often performed in conjunction with other groups having formal liaisons with TC 215 – CDISC, DICOM, GS1, ICN, IHTSDO, IMIA, UNECE, WHO, IHE, CEN, IEC. The relationship between ISO and CEN is long-standing and is formalized in the Vienna agreement. There is also a “pilot agreement” between ISO/TC 215 and HL7 that provides for normative HL7 standards to be brought into ISO for acceptance. Recent discussions at JIC and JWG information sessions have sought to clarify how and when these arrangements might be used and when work should be conducted as joint projects approved through the Joint Initiative Council.

7 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 council members.

Australian Delegate Attendance	Richard Dixon Hughes (Australian HoD) Heather Grain (Convener WG3)
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Substantive matters addressed during the Executive Council meeting included:

1. Welcome by the Chair of TC 215, Dr Christopher Chute (Mayo Clinic)
2. Content vs. framework.

The issues arising where defined terms and their definitions are repeated, in full, in another standard were discussed. ISO/CS is very concerned about this trend as it means changes in the original definitions and other content are often not reflected in later publications where the original work was repeated – leading to multiple concurrent definitions, potential inconsistency and inaccuracy.

¹ Source for all figures given in this section: TC 215 Work Plan spreadsheet (as updated to December 2010) and supplied by TC 215 secretariat shortly after the meeting.

Richard Dixon Hughes (Australia) reminded the Council of the implications of using dated as against an undated references to other standards documents and the dangers of ISO/CS insisting on a blanket approach. There are important health informatics standards documents that interpret terminology based on shades of meaning in particular definitions at a point of time. These documents need to be reviewed and potentially revised if the underlying interpreted definitions are changed.

3. Clarification of process for new work item (NWIP) ballots that gain the required majority of votes but fail because of a lack of the required number of experts from supportive countries.
4. Scope of TC 215. The proposed change in scope was approved – but is now subject to further review as part of the TC 215 reorganisation and business planning task force (reported separately).
5. Maintenance of elements that require frequent updating. Some activities within TC 215 generate standards and related code sets that need to be frequently updated.

Atsuko Saruhashi of ISO Central Secretariat gave a presentation outlining the key characteristics of the two principal ISO/IEC endorsed approaches that are available to assist in resolving this issue:-

- The Maintenance Authority (MA) – a standards development organisation that maintains normative content within a standard (the classic examples being the country code tables); and
- The Registration Authority (RA) which is an organisation contracted to ISO to maintain a register of elements that are based on a standardized framework, but are not part of, a standard. Examples include: ISBNs (International Standard Book Numbers) and OIDs (object identifiers)).

An MA must be an ISO member body, whereas an RA may be any organisation that performs the registration function under a contract with ISO. In either case, an MA or an RA requires ISO/TMB approval to be established.

With approval of ISO/Council, an RA may charge a fee limited to the recovery of the costs of providing the registration function.

The process for an MA to use in maintaining a standard maintenance must be defined in the standard.

ISO/TC 215 is looking to choose one or other of these approaches for maintenance of elements related to IDMP (identification of medicinal products) for WG 6.

Action: IT-014 needs to understand and look to work within any RA/MA frameworks established by TC 215

6. Harmonization Update

In his presentation to the Executive Council, Kees Molenaar, current Chair of the JIC, outlined progress in implementing the new three-tiered JIC meeting model and the new JIC website. The Joint Initiative Charter has now been in place for 5 years and needs to be updated to reflect changes over this period – the JIC has commenced this task.

More details on SDO harmonisation and the JIC is provided in section 10 below.

7. TC 215 Reorganisation and Business Planning Task Force (RBP TF)

Jeremy Thorp (UK NHS), Chair of the TC 215 RBP TF provided the mid-course report on the TF's activities, particularly in relation to proposed changes on the strategic mission and objectives for TC 215. See section 12 below for a summary of progress.

8. Editing ISO Standards

Atsuko Saruhashi of ISO Central Secretariat gave a detailed presentation to the TC 215 leadership on ISO/IEC editing rules (which are set out in Part 2 of the ISO/IEC Directives). This included advice on titling standards, provisions, scope, conformance provisions, normative references, self referencing, clauses, subclauses with and without titles, paragraphs and hanging paragraphs, notes, examples and lists.

The ISO/IEC directives and ISO Supplement are available for download from the ISO website at: www.iso.org/directives.

The tools and information being made available by ISO to assist in drafting standards is gradually being extended to include online tools such as a glossary with limited functionality and access to commonly used code sets (and the ISO Concept Database – CDB was demonstrated; see comments under SKMT later in this section)

9. Chair's report to Executive Council

Dr Chris Shute reported briefly noting that it was of concern that some P-member countries had been inactive in TC 215 affairs for quite some time and that they are in breach of the terms of membership. Letters are being sent to encourage their participation and/or obtain clarification of their intentions. As a practical matter, having inactive P-members makes it harder to progress the business of the Committee.

Efforts are continuing to secure broader participation from across the world and the possibility of "twinning" for developing countries is being investigated.

In addition, more active coordination with relevant ISO, IEC and ITU-T committees is being pursued actively – notably: TC 37 and ITU-T SG 17.

10. Change in TC 215 Secretariat

In May 2010, the Health Information Management Systems Society (HIMSS) announced that it is withdrawing from being the TC 215 Secretariat on behalf of ANSI (the American National Standards Institute) - the ISO national member body for the United States of America.

ANSI sought expressions of interest from other US-based organisations and has selected the American Health Information Management Association (AHIMA) will be advised by the US TC 215 TAG in selecting an appropriate organisation with compatible objectives to support TC 215.

11. Review of Current Liaisons. The TC 215 Secretary, Audrey Dickerson, reported on developments in relation to current and proposed liaisons.

NORMAPME (European Office of Crafts, Trades and Small and Medium sized Enterprises for Standardisation). The request from this European industry association for an active liaison at the level of TC 215 had been deferred from the previous TC 215 meeting for further advice, where it was found that the Category A liaison being sought was not considered appropriate. Canada had voted against the proposed liaison because of concerns that this group is not a standards organization, has a regional focus on protection of trade for Europe and does not have a clear collaborative interest with TC 215.

The Executive Council accepted the Secretariat's recommendation that NORADME be invited to seek Category D liaison with relevant TC 215 Work Groups – the applicable WGs yet to be established.

HON (Health On the Net). No further progress was reported in respect of the application from this health content monitoring and certification organisation for Category A liaison.

12. Process for establishing liaisons. The Executive Council was reminded of the formal process for establishing liaisons, which starts with preparation and submission of a "Liaison Statement" that is then voted on by TC 215. If the vote is successful, a formal invitation to establish a liaison is sent to the other body and the liaison is established if the other body formally accepts the invitation – and for ISO TCs this required a formal ballot of the TC members.

Members of the Executive Council observed that these formalities had not always been followed, leading to considerable confusion among other bodies and the standing of various liaison relationships.

13. Report on ISO Privacy Steering Committee (ISO/TMB/PSC)

TC 215's had two nominated representatives at the foundation meeting of the ISO/TMB/PSC in Berlin - Elaine Sawatsky (Canada) and Alessandra Pastorino (Italy). In their report they noted that:

- The Privacy Steering Committee was established by the ISO Technical Management Board (TMB) in response to an approach from the world's privacy commissioners.
- This initial event was more of a conference than a working meeting and focussed on the number of activities taking place in the privacy domain and establishing better communication
- A key question was how to bring the multiple initiatives together.
- TC 215 would wish to be involved at least to the level of a formal liaison and to maximise its input given the need for privacy standards to recognise the special needs that arise in health care delivery.

Lori Fourquet (Convener WG 4) reported that she had also attended the conference in Berlin and found it a very diverse group which included legal, technical and regulatory interests. TC 215 needs to review its documents from a privacy perspective.

Issues arising from the formation of the PSC were discussed in several sessions during the meeting including WG 4 with a further presentation being made to the closing mini-plenary.

14. Maintenance of defined terms - SKMT and ISO Concept Database.

Heather Grain reported to Executive Council on progress with implementation of the Standards Knowledge Management Tool (SKMT) for the health informatics glossary.

As one of the two leads of the SKMT joint project, Heather Grain also presented on SKMT in the JIC Open Forum, the JI Harmonization Track (where its progress as a joint project was considered) and to TC 215 joint sessions and at the Mini-Plenary.

A consolidated report on consideration of SKMT/Glossary in Executive Council and other sessions is provided in [section 13 below](#).

The Executive Council considered the relationship between the SKMT/Glossary and the ISO concept database, cdb.iso.org, which was demonstrated to the Council.

While TC 215 has agreed to move towards a position that all terms used have to be put into SKMT before a document is balloted, this is not happening. Project leads are supposedly responsible.

In discussion on how to apply the SKMT/Glossary capabilities within TC 215, Executive Council agreed that the procedure for alignment of terms and definitions in TC 215 will be to first seek

existing definitions from the TC 215 SKMT/Glossary, then to check the ISO CDB tool and then other ISO and other sources.

Action: IT14 to consider whether we should adopt the same procedure – SKMT first, then ISO concept database

15. Future meetings

With the active assistance of the Finnish standards national standards body, which was gratefully acknowledged by all delegates, the unfortunate clash between the May 2011 meetings of HL7 and ISO/TC 215 was averted. The forward programme for TC 215 was confirmed as follows:

23-27 May 2011	Kuopio, Finland	Plenary and WG Meetings
Oct 2011	Dates & location tbc (Beijing had been proposed but China was not present in Rio)	Joint Working Group Meeting

Korea was nominated as a possible venue for the JWG in 2011.

Other meetings in 2011 that have the potential to clash and/or compete with ISO/TC 215 include:

- AMIA: 25-27 May 2011 Orlando (limited conflict – different audience)
- HIMSS Asia –Pac: 20-23 September 2011 Melbourne
- HL7 May WGM: 16-20 May 2011 Orlando
- IHTSDO 11-15 April 2011 Denmark
- WoHIT 9-12 May 2011 Budapest

As some two-thirds of ISO/TC 215 P-members are from Europe, and there is a strong desire to harmonise with the activities of the European Health Informatics standards activities undertaken through CEN, the TC 215 Executive Council attempts to have at least one meeting a year in Europe - to be joint with CEN/TC251.

9 OPERATIONS AND HARMONIZATION (O&H) COMMITTEE

At each meeting of the TC there is a meeting of Convenors, Vice Convenors and Secretaries to coordinate activities of the meeting and the TC. The meeting is chaired by the TC 215 Secretary and is not open to other delegates.

Australian Delegate Attendance	Heather Grain (WG3 Convenor) Andrew Caswell (WG8 Secretariat)
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At this meeting the O&H session was held over lunch on Monday, 11 October and addressed the following topics:

- Internal Operations Workflow – Process for initiating and progressing Preliminary New Work Items
- Internal Operations Workflow – Pre- and post-meeting conference calls (for coordinating project work, allocation of projects to WGs and aligning WG agendas)
- Agreements and coordinated ballots arising from the harmonization process
- Review of the overall TC 215 work program – actions/changes arising
- Review/discuss templates used for resolution of ballot comments.

There was nothing of particular significance to Australia.

10 JIC HARMONIZATION ACTIVITIES

Australian Delegate Attendance	<p>Joint Initiative Council (JIC) Harmonization Task Force - Information session & open forum - Most delegates</p> <p>JIC Harmonization Track - partial attendance and input from:</p> <ul style="list-style-type: none"> - Heather Leslie - Richard Dixon Hughes - Anthony Maeder
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10.1 JOINT INITIATIVE COUNCIL (JIC)

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:

- A mutually agreed upon and used decision process for international standardization needs;
- 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 (which has just completed its probationary period to become a full member of the JIC). More information on the JIC may be found on the JIC website: <http://www.jointinitiativecouncil.org/>.

The JIC has largely completed a transformation in the way it operates, which has been underway since the beginning of the year when Kees Molenaar from Europe took over as JIC chair. Under the new regime, JIC has taken more direct control of harmonization activities and, in order to be more open, inclusive and informative, now has three types of meetings:

- The Joint Initiative (JI) **Open Forum**. The purpose of the Open Forum 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 and at HL7 WGMs and, as required, at major events staged by each of the other JIC members and are open to all who wish to attend.

- 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.

While open to the whole community, these meetings are structured and take place as an additional stream at ISO/TC 215 meetings – now being characterised as the "Joint Working Group – Harmonisation (JWG-H). This continues to be formally constituted as ISO/TC 215/WG9, although

under the new JIC meeting structure, it appears to have only a single chair/convener (Don Newsham from Canada), rather than one from each of the SDOs participating in the JIC.

Each of the JIC members had a formal representative present in these sessions in Rotterdam to interact with potential projects. Activity in the JIC Harmonization Track sessions is reported separately in section 10.3 below.

- **Joint initiative Council (JIC)** – which decides on its own membership, and the leadership of subsidiary bodies, new work and the resolution of issues regarding joint work. The JIC council meeting is the only closed meeting within the JI framework.

These changes were driven by a range of factors including an increase in size from three to six participating SDOs, experience over the first few years of JIC/JWG operations and the need for greater formal communication at executive level to ensure that joint projects progress satisfactorily.

Part of the change has been the repositioning of the "Joint Working Group" (JWG). Standards Australia used to provide the secretariat of this WG until early 2010 but concurrent with the new arrangements all JIC activities have been managed directly by the TC 215 Secretariat. This change in approach was signalled in the Australian delegation report from the May 2010 meeting.

All Australian JWG support activities have now been terminated and the previous website that we provided has been transitioned to archival status.

HL7 is hosting the new JIC website on behalf of the JIC Secretariat. This website holds registry of all projects, Inventory of policies and record of all meetings and agendas.

Outcomes for Australia

As noted in the previous Australian delegation report, the new format with a "JIC harmonization track" brings greater focus and formality to harmonization activities and is a considerable improvement but this has come at an additional cost in terms of the number of important issues that need to be addressed in parallel by the Australian delegations at TC 215.

10.2 JIC OPEN FORUM

The Joint Initiative Council (JIC) Open Forum commenced with a brief explanation of the Forum's role in the new arrangements for harmonisation of health informatics standardization activities through the JIC (as described above).

The Forum consisted of presentations accompanied by opportunities to ask questions about each of the following projects, which were also reviewed in the Harmonization Track and in relevant Working Group sessions. Only limited details are provided here where a project is reported in more detail in other sections of this report.

Existing projects

- BRIDG Model – presented by Bron Kisler (CDISC).

An earlier version of the BRIDG specifications passed both ISO/CD and HL7 ballots simultaneously in May 2010. CDISC released a new updated version of the BRIDG model in August with a further release being planned to incorporate the final resolutions of ballot comments and release to conjoint CDISC and ISO/DIS ballot anticipated in late 2011.

The Next ISO DIS ballot in May 2011, targeting an IS in ISO.

ISO has been approached to consider putting forward a CDISC board member.

For more detail on the BRIDG project, see [section 16.2 below](#).

- Individual Case Safety Reports (ICSR) – Tim Buxton (European Medicines Agency)

ISO 27594 ICSR will provide a standard form of reporting for adverse reactions and events when drugs are administered. It is based on a previous specification developed by ICH and has passed second DIS ballot in ISO/CEN and HL7. Following reconciliation of comments it was approved for release to FDIS ballot at this meeting.

- Identification of Medicinal Products (IDMP) – Tim Buxton (European Medicines Agency)

IDMP standards provide for unique identification of medicinal products around world – conjunction of name, dose and form – including information needed to specify factors such as routes of administration.

The IDMP series of standards went into the 5-month DIS ballot on 23 Sept. Ballot close 23 Feb 2011. Joint with CEN, co-terminate in HL7 on 23 Feb.

- EHR Systems Functional Model (EHR-S FM) – Gary Dickinson

Joint ballot of Release 2 (R2) of the EHR-S FM in ISO, CEN and HL7 will address issues and further work from HL7 and Other sources. This is a major update of the existing ISO 10781:2009 document to incorporate issues raised during application of the model in CCHIT and Canadian conformance testing, the interoperability model and lifecycle model (both DSTUs) plus implementation guides from CDA.

Majority of recommendations from Functional Profiles will be brought in to R2.

The plan is for a HL7 committee level ballot targeting May 2011 ballot cycle; with joint HL7/ISO normative ballot to close in September/October.

- Clinical Trial Registration and Results – Bron Kisler (for HL7)

This is a joint CDISC and HL7 activity approved by JIC in April 2009 with HL7 (RCRIM) as the lead.

This provides harmonised message exchange between clinical trials registry and largest trial sponsors, initially concentrating on US requirements. Phase 1 focuses on the registry, results will come later.

The Jan 2010 ballot addressed requirements for the US-NIH clinicaltrials.gov and WHO registries. New requirements were introduced last week at HL7 for a third group.

- Data Types

Technical edit has now been completed with Grahame Grieve yet to complete reviewing the edits to allow the document to go to its final FDIS ballot prior to publication.

Grahame Grieve is beginning a process to create a later revision with Patrick Lloyd, Canada, as co-lead. This will address further revisions that have arisen during the extended time (3 years) taken to finalise the document.

- SKMT/Glossary – Heather Grain

Heather gave a progress report addressing the same points that are covered in section 13 below.

- Patient/carer automatic identification and data capture – Christian Hay (GS1)

Christian provided a brief outline of the proposed 16-digit identification system addressing the challenge of defining a labelling format which secures auto ID data capture on a wristband in a single process involving product identification.

Work is starting with twice-monthly conference calls commencing Oct 19.

During review of this project in the JIC Harmonisation Track, IHTSDO requested becoming officially involved.

Pending projects, development work and other activities

There was preliminary discussion of the following projects which were considered in more detail during JIC Harmonization Track (reported in the next section).

- Data Types Implementation Guide
- Model for Dose Syntax
- Detailed Clinical Models

Feedback from the ISO Privacy Steering Committee was also discussed and it was noted that a full session had been allocated to consider the question of "Software as Medical Devices" – of interest to most of the SDOs participating in the JIC (see [section 11 below](#)).

As more details (including official minutes) become available they will be posted on the JIC website: www.jointinitiativecouncil.org

10.3 JIC HARMONIZATION TRACK

The JIC harmonisation track (JWG-H) commenced with an outline of the new three-level structure for JIC meetings in the role of the JWG-H in that structure.

Current JI-approved projects – progress reviews

The procedure for meetings of the JIC harmonisation track are still being refined; however, time was allocated for a detailed review of each of the following existing approved joint projects (which were also reported to the JIC Open Forum – refer to [section 10.2 above](#) for more information on specific projects and their development status).

1. Patient automatic identification data capture
GS1 Lead (Christian Hay) with ISO WG1 and now IHTSDO as participants.
2. Biomedical Research Information Domain Group (BRIDG) Model
CDISC (Bron Kisler)
3. Standards Knowledge Management Tool (SKMT) – Issues Review and Resolution
SMKT Leads (Heather Grain, Andrew Grant)
4. Clinical trials registry
HL7/RCRIM (Scott Getzin leading), CDISC (Bron Kisler)
5. Data Types – review status of final FDIS ballot
ISO/TC 215/WG 2 (Grahame Grieve)
6. EHR Functional Model (R2)
HL7/EHR Gary Dickinson) with John Quinn, Don Mon and ISO WG8 representatives also invited to be present.

7. Integrated Case Safety Report (ICSR) - passed DIS ballot, next ballot is FDIS
ISO/TC 215/WG 6 (Ian Shepherd -Convenor)
8. Identification of Medicinal Products (IDMP) – currently out to DIS ballot closing 23 Feb 2011
ISO/TC 215/WG 6 (Ian Shepherd -Convenor)

Proposals for new joint work

9. Data Types Implementation Guide

This is being proposed as a new Joint Initiative Work Item with Grahame Grieve and Heather Grain as leads. It needs to be progressed to NWIP stage in ISO before becoming a JIC proposal.

10. Drug Dose Syntax

Proposing to be joint with ISO/TC 215/WG 6 and HL7/Pharmacy (John Quinn to obtain lead) and likely CEN participation.

The business requirement looking at structure and content for dosing information – intent is to provide a standardised syntax to express dose information consistently to underpin for primary care, ePrescribing and secondary care orders.

In the mini-plenary the underlying TC 215 project was approved by for NWIP ballot as an ISO Technical Specification (with WG6 as the lead and CEN engagement via the Vienna Agreement).

11. Detailed Clinical Models/ Clinical Information Model

William Goossen (Work Item Lead), ISO – see detailed commentary in [section 15 below](#).

Other

12. Report of Joint Initiative Representatives to the Ad Hoc Task Group (to the ISO Privacy Commission) - Elaine Sawatsky (+others). Also reported to Executive Council
(See at: _13. Report on ISO Privacy Steering Committee (ISO/TMB/PSC))
13. Forum on Medical Device Software & Health Software Product Safety – see next section.

11 SOFTWARE AS A MEDICAL DEVICE (SAMd)

A special session of the JIC Open Forum was convened to address and share views on the emerging issue of regulators treating software as a medical device and bringing it into the regulatory regimes for such devices, including mandatory reporting and management of faults. Formal presentations were made by several speakers, with the initial presentation setting the scene.

1. Kees Molenaar (CEN/TC251 Chair) and Joe Kraus from the Ministry of Health, Welfare and Sport, The Netherlands on the EU Medical Devices Directives (MDDs)

Kees and Joe reported that there are three MDDs in the EU at present. They incorporate the "new approach" to device regulation, being to use harmonised standards as a means of demonstrating compliance with identified "Essential Requirements" relevant to each class of device.

Each directive aims to ensure that any medical device placed on the market can be recognized by the user, by its CE mark, as having undergone a suitable process of assessment by appropriate authorities and is safe and effective for use with any given patient and user.

Broadly speaking, each EU MDD lays out a definition of a device or accessory and the classification rules; laws, rules etc. relating to the advice; the essential (safety) requirements that each product must

fulfil before it is eligible to receive the CE mark; how to use harmonised standards as a means of demonstrating compliance with essential requirements; and compliance assessment routes.

In relation to software, the preamble to the relevant MDDs state "it is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device is a medical device. Software for general purposes when used in a health care setting is not a medical device."

The recent concerns have arisen from the addition of a new Essential Requirement to the MDDs which states:

"for devices which incorporate software or which are medical software in themselves the software must be validated according to the state-of-the-art taking into account the principles of development life cycle, risk management, validation and verification."

The consequence of this is that some software falls naturally and logically into the definition of a medical device under MDD 94/42/EEC(MDD) as amended by 2007/47/EEC and will be regulated under this directive as a medical device. However, the responsibility to provide evidence of compliance rests with the manufacture that places the product on the market under its own name. A difficult scenario emerges when clinical application software comes about through a consortium arrangement in which various parties come together and create a "system".

Considerable confusion has arisen (despite consistent warnings) over the undefined expression "stand-alone software". In attempt to assist the industry and resolve confusion, the DG Enterprise within the EC has formed a medical device expert group (MDEG) which handles the classification of borderline cases; however there is still concern that most of their expertise is in "conventional" devices.

It was also noted that:

- 'stand-alone' software used for clinical purposes was already a medical device under the old regime based on the previous definition that referred to "any article" which would include software;
- there were problems on the borderline with general-purpose software like operating systems and applications used in hospitals for logistics and/or financial purposes;
- different EU member states took different approaches to the borderline cases;
- an accounting package used in health settings is clearly not a medical device;
- "Class 1 software" can be self-certified, others need a notifying body (which restrict path to market);
- EHR systems are not medical devices - because the paper record was not a medical device;
- CDS and other expert systems are medical devices;
- Image archiving software is not a medical device;
- There may also be software "accessories" for medical devices, which achieve or add functionality and may be caught by the MDD regulations;
- There are still questions about operating systems and hospital systems which may interface with medical device software (e.g. logistics, patient data, insurance, name, date of birth ...).

2. Industry viewpoint – Martin Ellis, Chair Intellect Clinical Safety Forum, BT Health

An industry viewpoint was put by Martin Ellis of BT Health in the UK, who indicated that:

- Patient safety and risk are acknowledged to be part of health software products – industry accepts that patient safety is paramount;

- The issue is how to manage problems of software development and introduction;
- It is necessary to identify risks, document approaches, test and establish residual risks and communicate to customers as part of an end-to-end process
- In the UK, DSCN 14/2009 gives direction on how to manage such risks based on application of standards.
- Industry supports the aims of the revised MDD; however:
 - suppliers need greater clarity on how to interpret regulations which are difficult to apply to software;
 - the industry needs appropriate guidance and time to support change to the new regime;
 - an international standard is urgently needed for safety management of software not considered a medical device.

3. Provider viewpoint – Neil Gardner (COACH, Canada)

In Canada, a new medical device ruling was released in August 2009 with a notice in May 2010 providing for compliance by September 2011 for Class 2 medical devices (those requiring a higher level of assessment). There is ongoing dialogue with health Canada on the scope and application of the ruling, with considerable collaboration and interest among industry associations including COACH, ITAC Health, MEDEC and a conference having been held in early September.

CIOs and the vendor community are aligned with the professional association (COACH) in supporting a holistic approach to address the broader safety patient safety issues and, notwithstanding the scope of the SAMD deregulation. Some of the key points arising were:

- How to decide what are Class 2 systems?
- High level information is needed to guide clinicians on decisions with direct consequences for patients;
- There is a general desire for consistent practice regarding “product” and “process” with the following international standards playing potentially vital role:
 - Best practice standards for product: IEC 62304 (software design process), and ISO 13485 (QMS for construction of medical devices)
 - Best practice standards for process: ISO 80001-1 and ISO 25238.
- Define “ecosystem” for software development: design, implementation and maintenance.
- The desire is to have an integrated set of standards that are used in conjunction with each other and do not have conflicting requirements

TC 215 could support countries by working towards an integrated set of standards and best practices sooner rather than later, extending and better aligning current standards work, which often comes from the medical devices field. A technical report could be the first step.

4. Provider viewpoint – from UK BSI

The role of the regulatory bodies is to establish rules to certify devices, and to investigate incidents. In the UK, NHS has its own standards for software development and MHPRA regulates devices.

BSI contributed by forming a portfolio with experts within its IST 35 committee to focus on software as a medical device and actively support CEN with contributions to the European working group looking at borderline issues in classification of software as a medical device.

BSI has some concern at IEC TC 62 extending their scope to include stand-alone software. TC 62 has a medical device focus and needs to ensure that the software industry, consumers and regulators are effectively represented in its activities.

There is need for development of new harmonised standards to address the "Essential Requirement" of the European MDDs concerning software

5. Provider viewpoint - Björn-Eric Erlandsson, MPA, Sweden

Björn-Eric reported that the new EC directives are largely based on experience in his country, Sweden, and there have been guidelines for whether a particular software component falls within medical device category or not in Sweden for some time. However, he noted that 2007/47 EU doesn't resolve this aspect properly and made the following observations about interpretation of the MDDs:

- Software intended only for processing, storing and archiving patient data should not be qualified as a medical device, providing there is no manipulation of data.
- Software cannot be considered as a medical device simply because of the risk to data during handling (storage, transfer) because of malfunction of software or hardware.
- Functions such as display and search functions do not make software a medical device.
- Comments and feedback to the expert group is being sought.
- IVDs (In Vitro Diagnostic Devices) – some have been classified as medical devices and some have not. This is problematic because it is not consistent.

6. CEN/CENELEC Joint Taskforce:

Working on the "new approach" aspect of 2007/47 EU, and harmonising with other mirror groups such as TC 215, this Task Force is focussed on the following four aspects of the SAMD regime in Europe:

- (a) candidate definitions not well defined and ambiguous;
- (b) MDEG guidance comments are not being completely shared around the world;
- (c) understanding the standards not being widely discussed (not all companies participate);
- (d) transition to the future with other activities.

Relevance to Australia

This SAMD area is important due our local SME/SW industry being actively involved in software used for clinical purposes that may fall within the medical devices regime and the costs of obtaining information and the required certifications. We should consider supplying an expert to SAMD experts group.

12 TC 215 ORGANISATION TASK FORCE

ISO requires all its TCs to keep their Business Plans publicly available and up to date (annual revisions are common). As TC 215's Business Plan is already some years out of date, any further delay may become a compliance issue.

The ISO/TC 215 business plan was first produced in 2004 with an updated draft being completed in January 2009. This draft was reviewed by the Executive Council at the April/May 2009 meeting. The proposed acceptance of a revised version at the May 2010 meeting was unable to be progressed and the incoming TC 215 Chair sought a more fundamental review. The Executive Council meeting in May 2010 therefore agreed that a Task Force should be constituted to consider:

- the forward business plan for TC 215;
- options for reorganizing the work of TC 215 (including the designated Working Groups).

Richard Dixon Hughes and Heather Grain are both members of the TC 215 Organisation Task Force being chaired by Jeremy Thorp (UK NHS).

A progress report on the work of the Task Force was presented at both the Executive Council and at the closing Mini-Plenary, covering the following topics:

1. Task Force was constituted by the ISO TC215 Executive Council on Sunday 9 May 2010, with terms of reference to consider
 - the forward business plan for TC 215
 - options for re-organising the work of the Committeeand produce:
 - an interim report for the Rotterdam meeting in October 2010
 - a final report for the Finland meeting in May 2011
2. The scope of the interim report (presented at the Rotterdam meeting) was to:
 - provide an agreed description of scope and objectives for TC 215
 - identify potential organisational models
 - propose a process for the appraisal of these models, including appropriate assessment criteria
3. Work was progressed by monthly teleconferences held on 28 June, 20 July, 17 August and 13 September attracting 17 participants from 7 countries (Australia, Brazil, Canada, Finland, Netherlands, UK, USA), concentrating firstly on the TC 215 scope and objectives – with potential organisational models being a secondary consideration at this stage.
4. The main themes that emerged from the TF's work were:
 - The scope of TC 215's activities should have a broader view of health informatics; health (to include social care and wellness); and interoperability (to include full sense of contextual and semantic interaction – including measures that increase users' ability to trust health information).
 - The Committee's scope needs to be broader to encompass its cornerstone role in prioritising, harmonising and promoting standardization in the health informatics – as well as being a developer/adopter of standards
 - There is a need to clarify the respective roles of TC215 and the JIC – which are becoming increasingly complementary to each other – with ISO/TC 215 being the accepted forum of choice for publication of joint projects.

5. Definitions. The role of TC 215 as a health informatics committee should be based on acceptable, consistent definitions of health informatics, health and interoperability. The TF put forward the following as working definitions for review and discussion:

"Health informatics (HI) is the intersection of clinical, IM/IT and management practices to achieve better health. HI involves the application of information technology to facilitate the creation and use of health related data, information and knowledge. HI enables and supports all aspects health services". [adapted from www.coachorg.com]

"Health is taken to mean a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" [WHO]

"Interoperability describes a state which exists between two application entities, with regard to a specific task, when one application entity can accept data from the other and perform that task in an appropriate and satisfactory manner without the need for extra operator intervention. In the context of health informatics, this implies full end-to-end interaction of health records from origin to point of use." [adapted from CEN TR 14300:2002]

6. Scope. The TF noted the revised scope proposed at the October 2009 meeting and formally accepted by ballot in early 2010, which is as follows:

"Standardization in the field of information for health, and Health Information and Communications Technology (ICT) to promote interoperability between independent systems, to enable compatibility and consistency for health information and data, as well as to reduce duplication of effort and redundancies.

The domain of ICT for health includes but is not limited to:

- Healthcare delivery*
- Disease Prevention and wellness promotion*
- Public health and surveillance*
- Clinical Research related to health service"*

In considering this scope statement, questions asked included whether TC 215 is only about interoperability – and, if so, how does this relate to its interests and activities in areas such as patient safety, security, welfare etc and, also, whether it is sufficiently explicit that TC 215's scope encompasses aspects of social care and wellness that are implied by adopting the WHO definition of health.

7. Mission. Discussion indicated that the previous mission and objectives of the Committee were too narrow in terms of the domain (assumed definition of health) and activity (not just interoperability) and the following revised mission is proposed:

"enhance the use and interoperability of personal health information and clinical information systems throughout the world to support safe, efficient and effective health services."

8. Objectives. The proposed new objectives for TC 215 are to:

"make sure that required standards are available to address the needs of the member bodies, by

- prioritizing and co-ordinating the development of health informatics standards, maintaining a coherent view*

– *harmonizing existing and emerging health informatics standards to establish a global framework of consistent and common standards for health systems and health data adopt or, where identified gaps necessitate original work, develop standards and specifications for health systems use and interoperability review and maintain standards in use, and provide access and support for emerging and developing countries."*

9. Success Criteria for TC 215. The following are proposed:

- (a) *Fewer standards (developed directly by ISO/TC 215 itself)*
- (b) *Prioritisation of needs*
- (c) *Engagement – through both Member body participation and the adoption and use of standards*

10. TC 215 Organisation. This is the principal focus for the second stage of the TF's work and is largely still work-in-progress; so further input is greatly welcomed.

Potential organisational models under consideration for managing the detailed work include sub-committees (not favoured by most); work groups (as longer-term functional entities or as smaller building blocks); portfolios; task groups; summits; and others.

Consideration is also being given to the constitutional role and function of Executive Council and the special task forces which report to it from time to time, making greater use of Cross-TC Joint Working Groups and International Workshop Agreements.

11. Success criteria for TC 215 Organisation. The following are among the criteria by which the success (or otherwise) of the future TC 215 organisation may be assessed:

- Meeting TC 215's objectives
- Availability of resource
- Effectiveness
- Cost
- Sustainability

12. Classification of work groups and other sub-groups.

Examination of the way in which work is distributed among the existing TC 215 WGs indicates that there is not a strong connection between WG titles and scopes and some of the work actually being progressed. Often the decision to allocate/allow a WG to undertake a project seems to have been driven by convenience for those involved, rather than the nature of the project. Alignment with the four groups in CEN 251 was also an initial consideration.

Potential different types of WGs/sub-groups that might be used to progress work within TC 215 was the subject of initial consideration by the TF in the interim report, and included:

- WGs for health informatics Infrastructure/infostructure (considered likely to be required on a permanent basis)
- Domain groups (less required and possibly on a temporary basis)
- WGs for research (the TF is not sure and still needs to clarify what this means with the proponents for adopting it).

The next steps for the TF will be to revisit the document in light of comments received during discussion at the Rotterdam meeting and conduct a further series of teleconferences – particularly to consider the question of TC 215 organisation and sub groups. It is also planned to seek input on the findings of the interim report from:

- Input from other associated SDOs and liaisons, e.g. CEN, HL7, other JIC
- Input from NMBs that are P-members and O-members of TC 215.

During discussion there was general support for the work of the TF and the comments in the Interim Report. The final deliverable from the Task Force in May 2011 will make formal recommendations for the organisational structure of TC 215 and its working groups.

Action: Richard Dixon Hughes and Heather Grain to keep IT-014 informed of the activities of the TC 215 business planning and reorganization task force and the alternative structures for TC 215.

Action: IT-014 to ensure that the business plan and on-going organisation will address Australian needs effectively.

13 SKMT/GLOSSARY JOINT PROJECT

Heather Grain reported to Executive Council on progress with implementation of the Standards Knowledge Management Tool (SKMT) for the health informatics glossary. While TC 215 has agreed to move towards a position that all terms used have to be put into SKMT before a document is balloted, this is not happening. Project leads are supposedly responsible. Bernd Blobel (Germany) echoed these concerns and indicated that DIN has identified some changes that are now required.

The Executive Council supported Heather's request for a stronger process to ensure that items do not go to ballot unless they have had their content harmonised and entered into the SKMT. It was agreed that secretaries would check the work and if not harmonised or entered return the work to the project leader to complete these activities. Process is that the secretary will, on receiving a document for ballot:

1. Checks document is in SKMT; if not, return to project leader for entry and harmonisation
2. Checks all defined terms are in the SKMT/Glossary; if not, return to project leader for entry and harmonisation
3. Checks that the terms are harmonised - that there is a harmonisation proposal in the documentation; If not, then check terms to see if there is more than one definition for the term and in that case send back to the leader requesting harmonisation proposal.

Adoption and use of SKMT/Glossary is being actively investigated by the other SDOs in the health informatics domain through an approved JIC joint project focussed on harmonisation of terms and definitions. A document has been prepared on the processes for harmonisation of terminology – which allows each JIC member to retain jurisdiction over their own terminology by declaring context, while still participating in the harmonisation process.

As one of the two leads of the SKMT joint project, Heather Grain also presented on SKMT in the JIC Open Forum, the JI Harmonization Track (where its progress as a joint project was considered) and to TC 215 joint sessions and at the Mini-Plenary. Key points made in these presentations included:

- Over 2000 terms have been entered and there are still many more to do. The terms that have been entered are not being actively administered, with many more terms still to be included.

- Additional levels of organisational engagement need to be defined
 - Record details of all documents/projects
 - Record an organisational glossary only to which terms and definitions are linked

This presents a maintenance problem, as the tool will not be able to identify stakeholders within the organisations
- Harmonisation process for terms used by multiple organisation is in trial.

The agreed harmonisation process is founded on the following key principles:

- No change to past documents (other than through proper consensus-based amendment and/or revision processes)
- Each organisation controls their own entries and requirements
- Documents and definitions within them do not change, even though the glossary may – as they are formally balloted content that exists until amended
- Glossary may indicate that a term in a current document is now ‘retired’ – not for future use.
- Reports of terms in documents can be provided indicating retired and ‘standard’ terms to assist in updates

Action: IT-014 to consider formal adoption of the same process (previously noted under Executive Council)

ISO have also implemented a concept database, which is available at cdb.iso.org. A practical demonstration of the database was also given to the Executive Council.

Given its experience in developing and using SKMT, the possibility of TC 215 being more active in working with ISO on the harmonisation of definitions was raised. In response, the Executive Council noted that both Melvyn Reynolds and Andrew Grant from TC 215 were involved with Rinehart (ISO) when the ISO concept database was set up. Melvyn Reynolds reported that one of the key TC 215 lessons that had been shared was the need to allow TCs sufficient flexibility in the maintenance of definitions and terms within their own domains.

Stefan Sauermann (Austria) indicated that he was looking for a more automated interaction via an API or, alternatively, allowing export to a local terminology services environment – for use as a secondary source. Chris Chute noted that there is an ISO standard for terminology standards. It was also suggested that linkages with the NCBO (National Center for Biomedical Ontology) at Stanford University might also be productive. Heather welcomed the suggestions.

14 WG 1 - DATA STRUCTURE

Australian Delegate Attendance	Heather Leslie, Evelyn Hovenga Richard Dixon Hughes (WG8 joint topics) Andrew Caswell (WG8 secretariat) Occasional attendees: - Heather Grain, Anthony Maeder
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Most of the WG1 program was held jointly with WG8 (EHR Business Requirements) and with CEN/TC 251/WG 1 with the chair alternating between convenors.

Some 70 delegates attended the WG 1 and WG 8 sessions, representing 19 countries and at least 2 liaisons (WHO & HL7).

ISO/CD 13972 Detailed clinical models

There has been considerable local interest and some controversy over the work on *ISO/CD 13972 Detailed clinical models*. This project was discussed in a dedicated meeting of the project team as well as in presentations to WG 1 and WG 8 and to the JIC Harmonisation Track. Given the breadth of this topic and the level of Australian engagement and interest, it is separately reported in [section 15 below](#).

14.1 BACKGROUND PRESENTATIONS

Standards implementation and large scale initiatives

There was discussion on the following perspectives presented under the topic of "Standards implementation and large scale initiatives" with WG 1 chair, Prof Stephen Kay (UK) presiding.

The use of standards in Brazil

Dr. Lincoln Moura provided insights into some aspects of the Brazilian experience with HIS and their use of standards – particularly in relation to the inter-relationship between international statistical reporting formats and the health informatics standards used for system interconnectivity.

The following points were made in discussion:

- There were many questions about SDMX-HD (statistical data metadata exchange health domain - an ISO standard which is commonly used in the banking industry). It allows for data exchange between different domains with real-time monitoring.

Since there was little familiarity with this issue, it was suggested that there may be a gap in TC 215's understanding and that further discussion should take place later. It was proposed to delegate further discussion to a specialist special interest group.

- Dr. Krishnamurthy (WHO) raised a question regarding the collaboration method and the costs related to the south-to-south collaboration. Dr. Moura answered that there were political issues, which they were working their way through. Regarding the cost, there was funding of about USD 1 million for two years to develop the standards. In addition, an education programme was important detailing the steps necessary to implement the standards.
- The Brazilian initiative was under the auspices of PAHO (the Pan-American Health Association).

- Ms. Marinho (Brazil) indicated that appropriate infrastructure was needed in remote areas, such as the Amazon region. Military infrastructure already existed, which would need to be opened to public use. She also stated that, even in these very remote area, 0-6 immunisation coverage was 76-79%.

Framework for National Information Systems (NWIP ISO/TS 16555)

Dr. Ramesh Krishnamurthy (WHO) provided an overview of different national health information systems, where health data has been recorded in various ways. Since standards remain an important platform and the most viable way for strengthening a country's broader Health Information Systems (HIS), he proposed a NWIP to establish the links between this broader HIS framework and its components to the corresponding ISO standard(s) and to the business requirements for the eHealth Architecture (ISO 14639).

The following points were made in discussion:

- It was questioned whether the proposed standard can be adapted from a developed country to developing country and vice versa, given the fact that some developed countries (such as USA, Australia, and some of European countries) were not participating in developing the standard.
- Mr. Klein felt that developed countries had robust existing frameworks and, hence, less need for the Health Metrics Network (HMN).
- Dr. Krishnamurthy believed that the evolution of the Roadmap from v3.0 to v4.0 would make it usable by a wide range of countries.
- He felt that the codification of this framework would mean integrity of data and strategic investment for those countries who adopted it.

Dr. Lyver, chair of WG 8, which has carriage of this work item, reminded delegates that the NWIP ballot for ISO/TS 16555 has been launched, and members should be able vote in the next few days. Although there has been a shortage of experts to date she would be making a further call-for-experts and encouraged anyone who was interested and could possibly contribute to put their name forward.

Approaches and tools for harmonisation

The following material was presented in a joint WG 1/WG 8 segment on the topic of "Approaches and tools for harmonisation" with Pier-Angelo Sotille of CEN/TC 251 leading discussion:

Use case template for projects under Mandate 403

Prof. Kay presented a use case template that is being proposed as a TR following on from the European health informatics projects under Mandate 403 and provided an update on the project, including the status of Mandate 403 at the European Commission. Matters raised during discussion included:

- The misuse case, guarantees of security and safety issues. The safety case was important for the NHS, while security could be covered. It was noted that these questions of misuse and patient safety are addressed explicitly in the template.
- There was an opinion that a repository of interoperability issues would be very useful if it was shared with other parties. A preliminary report was expected to be completed by the end of the year, and once revised would go to ballot. Thereafter, the TR should be available for review.
- The single template (UML diagram) was related to the use cases model, and was meant to give an overview of the relevant items.

Standards and implementations

The following material was presented in a joint WG 1/WG 8 segment on the topic of "Standards and Implementations" with Prof. Stephen Kay, WG 1 chair, leading discussion.

ISO 13606 EHR communication in Sweden

Dr. Hakan Nordgren and Dr. Karl-Henrik Lundell presented the Swedish 3-layer approaches for EHR communication and announced that there would be a seminar on the Swedish e-health approach in Lund on 2-3 November [it may be useful for Standards Australia to obtain a copy of the papers to assist with the 13606 item on this year's work program].

The following key points were noted:

- The effort was originally aimed at achieving longitudinal health records in Sweden, but this not presently possible for political reasons.
- The approach uses a single unique identifier.
- For the process to be applied at national service level, support at a national level is necessary. On the implementation side there were three levels of applications.
- It is important to consider the way in which clinical data is to be shared.
- It was questioned why this work item was not initially proposed as part of the work program at the European level. The response was that it was intended to be elevated to the European level once the concept had been established.
- Early indications are that clinicians welcome participation in the project.
- The methodology used relies on harmonised reference information models.
- There were still no actions regarding the issue of harmonised reference information models by ISO WG1 or by CEN WG1. The Convenor invited the working group members to follow up.

WG1 invited countries to introduce and to share their best practices and/or approaches in developing their standards at a national level.

Action: The Swedish experience with ISO 13606 communications is of relevance to items on the current IT-014-09 work program and should be followed up by obtaining more information.

14.2 OTHER TOPICS COVERED

- A Joint meeting of WG 1 with WG*8 and WG 6 in the area of "**Requirements, frameworks and architectures**" was hosted by WG 8, which addressed the following work items reported in section 20 below (WG 6 Medications and Pharmacy Business):
 - IDMP Update (Mr. Ian Shepherd) - all 5 standards are in DIS ballot until 23 February 2011.
 - Proposed Generic model for dose syntax
- *ISO TR 14639 eHealth Enterprise Architecture for Emerging and Developing countries* was presented by Mr. Patrick Whitaker and Dr. Beatriz de Faria Leao. Discussion of this WG 8 project is reported further at section 22.1 below.
- *ISO/DTR 13054: Standards Knowledge Management*. Dr. Andrew Grant provided an update on the status of the project, including a demonstration of SKMT as part of an integrated standards

knowledge management ecosystem being tested with the ISO TR14649 (recommendation of further action on this is a matter for WG 8)

- *ISO 14199 BRIDG Domain analysis model for protocol driven biomedical research.* Mr. Bron Kisler (CDISC) provided a status report on the BRIDG project to a joint session of WG 1 and WG 8. This is one of the approved JIC harmonisation projects being managed by WG 2 within TC 215 and is reported in more detail in [section 16.2 below](#).
- *ISO 21667: Health indicators conceptual framework* - this document had passed FDIS ballot and was in the final stages of publication at the time of the meeting [and was finally published on 26 Nov 2010]. There is considerable interest in the document at national level in Australia.

Australia will now need to consider this standard for local adoption.

- *ISO TS 16223 Standards convergence to promote EHR interoperability* – Gary Dickinson presented the results of NWIP ballot / disposition of comments, which had failed to attract the requisite number of experts. The activity will stay as a work in progress, but will not be replaced for balloting yet. A further draft for consideration is expected by April 2011.
- Others reported under WG 8, including:
 - *ISO FDIS 18308*
 - *ISO NWIP 16527 PHR-S Functional Model v1.0*
 - *ISO 21667: Health indicators conceptual framework* - finally published on 26 Nov 2010.
 - *ISO 10781: EHR System Functional Model - Release 2.*

15 DETAILED CLINICAL MODELS (DCM) PROJECT (ISO/CD 13972)

15.1 SUMMARY

The project lead, Dr William Goossen, reported on DCM project activities to the JIC Open Forum and JIC Harmonization track as well as leading detailed discussion of the project in WG 1.

Australia is a significant contributor to this work as well as being a significant critic of some aspects and has provided much of the input and expertise, while having voted against the work (as proposed) – on the grounds that it was not sufficiently advanced to become the basis of a full International Standard.

Following detailed discussion at the previous meeting, it was agreed that the project would initially focus on quality measures applicable at the various stages of the DCM lifecycle and would not prescribe a single representational technology. Notwithstanding this agreement, the document continued to promote a single UML-based modelling paradigm for representation of clinical content. This was challenged in both the JIC Harmonization Track and WG 1 by Australian representatives with consequent agreement being achieved on a new structure.

Action: IT-014-09 to continue oversight of Australian engagement and assisting Australian experts Heather Leslie, Richard Dixon Hughes, Stephen Chu and Evelyn Hovenga to contribute to their respective parts.

15.2 UPDATE ON PROGRESS

The project lead, Dr William Goossen (The Netherlands) reported that there had been progress on preparing the draft through the middle of the year (Northern Summer) on the 5 substantive parts:

1. Clinician involvement
2. Content specification
3. Modelling
4. Repository & governance
5. Patient Safety

Activities that had taken place in recent months included:

- New introductory material had been provided by Australian experts (largely through Evelyn Hovenga) and is being incorporated
- Work was underway to put DCM into an architectural framework
- Earlier contributions had now been incorporated into the document

15.3 DISCUSSION

- The principal issue remains the requirement for UML to be used for expression of the DCM. Whilst it has been agreed that UML should not be a presentation format for clinicians, it may be considered as one technical expression of the generic DCM.
- There is a need to get the complexity under control:
 - Identify types of DCM

- What it is and what it is used for :- observations, actions, meetings etc
- Not too complex wholes eg prescription is already too complex for DCM
- Representation of DCM in many languages – there is a need to keep the semantics intact despite the language expression

The Joint Initiative Council DCM proposals

The JIC was presented with proposals for the 13972 work and apparently, also, the HL7 work on methodology and derivation of instances – although the latter has not been sighted. The JIC therefore have under consideration two items related to detailed clinical models, one from ISO and the other from HL7 (although apparently without official HL7 support), with the 13972 work now split into two parts.

John Quinn (HL7 CTO) sought two weeks to get feedback on the proposed HL7 DCM work components from the TSC and MnM group.

Once it is submitted formally to JIC SDOs then approval/disapproval will be made by email ballot, so a decision should be known by the November JIC meeting. [It appears that without HL7 support the methodology and instances work is not likely to become a project in JIC at this time.]

15.4 KEY OUTCOMES

The DCM project expert group recommended that the work on ISO/CD 13972 be separated into two work items: - one related to quality attributes of the models; and, the other related to the control processes required in the production of the models. This provides two sides of the quality equation.

The expert group's recommendations were taken up by WG 1, with a WG 1 putting forward a recommendation approved by TC 215 in mini-plenary to:

"split the draft document prEN ISO 13972 *"Health informatics - Quality requirements and methodology"* into:

Part 1: prEN ISO 13972-1 *"Health Informatics - Quality processes regarding detailed clinical model development, governance, publishing and maintenance"* and

Part 2: prEN ISO 13972-2 *"Health informatics - Quality attributes of detailed clinical models"*.

Other key changes were agreed in moving to the next steps included:

- Dr Goossen separating the documents.
- Moving forward with the two parts as draft materials for the next ISO meeting in Helsinki. These could potentially move through ISO at different rates.
- Improving collaboration among the experts working on the project – by organising regular teleconferences, communications and a wiki.
- Confirmed being received the draft project materials may be shared with other groups working on standardization and implementation of detailed clinical models.

15.5 COMMENTS/AUSTRALIAN CONTEXT

Dr Heather Leslie contributed the following observations [edited for this report].

This work item is consuming an enormous amount of energy directly and behind the scenes, totally out of proportion to the proposed gains. There appears to have been a similar experience in the Cambridge HL7 meeting recently.

- Separation of the work into two sub items seemed to appease most people to some degree. Some consider that the process component of the work will progress relatively easily and that the attributes of the models themselves might even founder.
- There are substantial and diverse political forces also impacting on this work – HL7, CEN/HISA, ISO and NEN – all pushing/pulling in different directions and contributing to the confusion and unco-ordination.
- HL7 balloting of instances was complicated by a lack of insight into the ISO work. There was in-principle agreement that the ISO work could be shared with the HL7 collaborators as needed. A number of options were discussed. It was not clear which was the final solution – the project lead co-opting HL7 members of the expert group (but this cannot occur without confirmation from their national member bodies); individuals joining WG1 (but this needs confirmation from the member bodies as well). JIC are now considering these issues in the broader context of progressing harmonisation projects.
- According to Charlie McCay (departing co-chair of the HL7/TSC), there are at least 12 and more likely ~20 clinical modelling processes currently within HL7. He has suggested creation of a live, updated registry of modelling projects in HL7, with intent to try to harmonise internally.

There is potential to bring the registry and/or governance to JIC and perhaps to tie in with SKMT/Knowledge management plus the quality criteria work. Apparently Don Mon of AHIMA (HL7 chair-elect) has agreed to pull together the registry but this is not confirmed.

- The current draft document is dense, repetitive, full of jargon and still poorly constructed. The Australian contribution has been heavily edited by addition of text and has become much less clear. The document (or derived pair of documents) will need extensive editing and attention to detail.
- In general there is huge confusion about this work item, especially targeting an IS and starting in such an unformed manner. There may be further progress if the attributes portion of the work was downgraded to a TR, incorporating an environmental scan of all other activities to ensure that these are considered in this work.

Australia needs to adopt an approach to clinical content modelling as a matter of urgency and we are not unique. Other national programs are facing similar issues to NEHTA in developing consistent and safe documents/messages for sharing critical health information, much less the full complexity of an EHR. The current incrementally innovative approach by using messages and standard documents to 'patch' between current information systems will give us some progress, but it is limited and unsustainable into the future. Consideration of openEHR or equivalent as an EHR architecture should be a high national priority.

The detailed clinical model work on instances might contribute to some harmonisation around clinical modelling approaches, but the practical gains will not be realised for many years at best, and I suggest that we cannot afford to wait that long. It is very likely that this part of the work will not succeed in its current incarnation. I know that others are considering alternative approaches.

16 WG 2 - DATA INTERCHANGE

Australian Delegate Attendance	Klaus Veil Anthony Maeder (Telehealth topics)
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This meeting of WG 2 was attended by a total of 19 participants from 9 countries: Australia, Brazil, Canada, UK, Israel, Japan, South Korea, Norway and USA. The WG 2 meetings were again productive with a number of notable outcomes across the spectrum of messaging standards.

The current leadership of WG 2 is as follows:

- **Convener:** Michael L Glickman (USA)
- **Vice-Convener:** Michio Kimura (Japan)
- **Secretary:** The WG 2 secretariat has been vacant since Adrian Stokes (UK) withdrew at the October 2009 Durham meeting.

Klaus Veil (Australia) had been invited to take on the role but IT-014 and Standards Australia had not seen resourcing this role as a current priority for Australia.

WG 2 has two Special Working Groups:

- **Architecture Breakout Group ("SWG 2")** - Lead: Gary Dickinson (USA)
- **Methodology Breakout Group ("SWG 3")** - Lead: George "Woody" Beeler (USA)

Following discussions at October 2009 and May 2010 meetings, on this occasion, both Groups met as part of the general WG 2 sessions. WG 2 is considering merging the two SWGs back into the parent Work Group.

16.1 WG 2 SCOPE AND SUMMARY OF ACTIVITY

Among other things, Working Group 2 "Data Interchange" ("WG 2") deals with e-health messaging and communication standards submitted to ISO TC215 from other organisations such as HL7, IHE, 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 it the forum through which HL7 standards including V2.x, V3 RIM, CDA and the HL7 HDF were progressed to become international standards.

The current WG 2 work on genomics, data types and the BRIDG model also originated in and closely parallels work within HL7. On the methodology side, WG 2 is the vehicle for recognition of IHE processes within the ISO community. Conformance testing and compliance and quality are now seen as part of WG 2's scope.

Standards being progressed and maintained by WG 2 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 in which they originated.

All current WG 2 projects were reviewed and progressed at the meeting, two new Work Items were considered and one item of new business discussed:

- Domain Analysis Model for Protocol-driven Biomedical Research – commonly referred to as the "BRIDG" model

- HL7 Clinical Genomics - Pedigree Project
- Terminology binding to models (eg. the HL7 Reference Information Model "RIM")
- IHE Integration Profiles
- Web access to DICOM imaging objects ("WADO")
- Clinical document registry federation
- Quality criteria for services and systems in telehealth
- New Work Item for Clinical Trials Registration & Reporting
- New Work Item for regular HL7 RIM Updates
- New business item on Mobile Health using mobile/smart devices

In summary, the work in the ISO TC215 Working Group 2 progressed well and, where applicable, Australian issues and requirements were addressed. Five resolutions were commended to the Closing Mini-Plenary Session, which were approved. A number of actions from the meeting were identified and are covered further below.

Summary of outcomes

<p>Working Group 2 Communications Topics</p>	<p>This group is working on several joint initiatives including:</p> <ul style="list-style-type: none"> • <i>BRIDG V3.0.2</i> currently out for DIS ballot • NWIP "<i>Clinical Trials Registration & Reporting</i>" • NWIP "<i>HL7 V3 Reference Information Model - Maintenance Release Process</i>" <p>The two foundation TRs on IHE process and profiles (of interest to Australia) had still not progressed but another person was appointed to facilitate their finalization.</p> <p>As much of the WG 2 work draws on HL7, IHE, CDISC work or is in areas where Australia has not been active, WG 2 engagement has been a lower priority for Australia – except for the area of telehealth; however, closer attention is warranted to ensure joint work is completed.</p>	<p>IT-014 IT-014-06 and sub-groups</p>
<p>Working Group 2 Telehealth</p>	<p>WG 2 is also progressing two documents of interest in the area of telehealth:</p> <ul style="list-style-type: none"> • TS "<i>Quality Criteria for Services and Systems in Telehealth</i>" • NWIP for a TR "<i>Provisions for Health Applications on Mobile/Smart Devices</i>" 	<p>IT-014-12</p>

16.2 THE BRIDG MODEL

The "Biomedical Research Integrated Domain Group" is a collaborative effort to produce a shared view of the dynamic and static semantics. Its scope is protocol-driven research and its associated regulatory artefacts, i.e. 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 ISO/TC 215 work item is "*Domain Analysis Model for Protocol-driven Biomedical Research*" and is also an approved joint project on the JIC work program being led by CDISC with simultaneous approval taking place in ISO/TC 215 and HL7.

The scope of the proposed standard is a domain analysis model that provides a shared view of the dynamic and static semantics for the protocol-driven biomedical research domain. The primary purpose is to provide a global domain analysis model (DAM) for anyone involved in protocol-driven biomedical research or for anyone in healthcare informatics, who provides data for research and related purposes, such as post-marketing surveillance. The BRIDG DAM streamlines information flow from protocol 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.

Active participants in the BRIDG work have predominantly been US-based: CDISC, NCI, FDA and HL7.

Work Item History

May 2009: ISO NWIP approved

Approved as JIC project in 2009

Oct-Nov 2009: Balloted by CDISC and became an official CDISC standard

May 2010: Balloted as ISO Committee Draft ("CD") & HL7 Standard

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

Progress at this Meeting

CDISC Liaison Bron Kisler provided updates on the JIC project at the JIC Open Forum, the JI-JWG Harmonisation Track and WG 2 (refer BRIDG Update Slides N0715).

In summary, JIC-approved material should go forward with the current version of BRIDG V3.0.2 (released August 2010) without the content items that have not achieved consensus, so implementers can start using the standard. V3.0.2 also addresses most of the ISO and HL7 International ballot comments.

The Working Group agreed that any content that has not yet achieved inclusion would be handled in BRIDG Rel. 4

Julie Evans attended by teleconference to outline the BRIDG ballot comments (total 257) - refer to Julie's slide 1 (refer document N0721)

The Work Group spent some time discussing the remaining 55 comments and exploring if they are a barrier to publishing BRIDG V3.0.2. Julie confirmed that the 2-3 balloters of these comments are happy for V3.0.2 going forward, so assuaging concerns of the Work Group. It was recommended that these 2-3 balloters be contacted to ensure that they feel that their ballot comments have been addressed.

WG 2 agreed that BRIDG V3.0.2 including the resolved 257 ballot comments be submitted to CS by November 2010 so it can be published as a DIS by December 2010 in order for the disposition of ballot comment to be undertaken at the May Meeting in Finland.

Outcomes for Australia

Topic	Issue/Action/Recommendations	Owners
BRIDG	<p>It is not clear that the BRIDG standard currently has any strong strategic importance for Australia. However, CDISC is holding a 2-day education session January 12-13 in Sydney after which this view should be re-assessed.</p> <p>Action: To review the importance of BRIDG with relevant stakeholders after the CDISC education courses in January 2011.</p>	<p>IT-014 Standards Australia NEHTA</p>

16.3 NEW WORK ITEM PROPOSAL "CLINICAL TRIALS REGISTRATION & REPORTING"

The scope of this proposed standard ("CTR&R") is to create a data exchange standard (domain analysis model and data interchange specification) to meet the current global requirements for clinical trial registration and clinical trial results reporting.

The primary purpose of Clinical Trial Registration & Results (CTR&R) 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). The CTR&R exchange standard is intended to meet the current global requirements for clinical trials registration (part 1) as well as reporting of the results (part 2):

Clinical Trials - part 1: Registration

Clinical Trials - part 2: Results

The CTR&R standard 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. In doing so, this effort 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.

Progress at this Meeting

CDISC Liaison Bron Kisler outlined the NWIP (refer WG 2 document N0716) and the Working Group applied some text edits. The stated objective of the Proposal is to ensure that the balloting proceeds in synch at ISO, CDISC and HL7 International (RCRIM Work Group) and all were comfortable with this approach. If any of the experts in the three organisations has issues, they can raise these with their organisations. A resolution was proposed and passed by TC 215 to circulate the proposal for "*Clinical Trials Registration & Reporting*" for NWIP ballot.

Outcomes for Australia

Topic	Issue/Action/Recommendations	Owners
CDISC NWIP	<p>It is not clear if and how this proposed standard would be used in Australia. However, the FDA,CDISC is holding a 2-day education session January 12-13 in Sydney after which this view should be re-assessed.</p> <p>Action: To maintain a watching brief on this NWIP and review its importance after the regulatory organisations session in January 2011.</p>	IT-014

16.4 HL7 CLINICAL GENOMICS - PEDIGREE PROJECT (ISO 13449)

This Work Item deals with pedigree representation (including visualisation) providing standard clinical representation not seen as suitable for other Health IT purposes.

This Work Item was accepted 16 May 2009 with experts nominated from Brazil, Germany, Japan, UK and USA.

In October 2009 it was agreed that the document be submitted to the ISO Central Secretariat as Draft International Standard ("DIS") under the ISO/HL7 fast-tracking agreement. All materials have been sent to CS for publication for ballot.

Outcomes for Australia

Topic	Issue/Action/Recommendations	Owners
Clinical Genomics	<p>This is a HL7 International Standard. In line with Australia's commitment to HL7, ballots of this Work Item should be supportive.</p> <p>Action: Australia to consider voting in favour of this Work Item when it comes to ballot.</p>	IT-014

16.5 NWIP FOR HL7 RIM UPDATE (ISO 21731)

In 2005, ISO TC 215 approved ISO 21731, "Health informatics: — HL7 version 3 — Reference information model - Release 1". Subsequently, HL7 has an ongoing maintenance process that produces a new release of the HL7 Reference Information Model (RIM) annually. Release 3 of the RIM has passed HL7 ballot for release late in 2010. This project 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. Starting with Release 3, the HL7 RIM has been formally bound to the data types in ISO/FDIS 21090.

Progress at this Meeting

The Work Group agreed that the HL7 International Reference Information Model ("RIM") ISO standard 21731 needs to be updated. This will use the most recent RIM version at the time of the ballot (RIM V2.33 is expected to be RIM V3).

We also need a prototype Maintenance Process to ensure that ISO 21731 stays up-to-date. This is to be discussed with the ISO Central Secretariat Technical Program Manager. We believe we need a two-stage process:

- Eligibility (Scope)
- Validation & Balloting

The NWIP proposal form (N0718) was completed and approved with the US, Canada, Australia, Korea, Japan and The Netherlands (tentative) indicating that they expect to be supporting NMBs.

A resolution was proposed and passed by TC 215 to circulate the proposal for "HL7 V3 Reference Information Model - Maintenance Release Process" for NWIP ballot.

Outcomes for Australia

Topic	Issue/Action/Recommendations	Owners
HL7 RIM Updates	<p>This is a HL7 International Standard. In line with Australia's commitment to HL7, ballots of this Work Item should be supportive.</p> <p>Action: Australia to consider voting in favour of this Work Item when it comes to ballot.</p>	IT-014

16.6 IHE INTEGRATION PROFILES (ISO TR 28380)

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.

Work Item History and Progress at this Meeting

The Work Group has been waiting for some time for volunteers to reformat Parts 1 and 2 of TR 28380.

Charles Parisot had agreed to reformat Parts 1 and 2 of TR 28380, but this had not yet been done. Michael Nusbaum has offered to organise the completion of the edits, after which they can go to CS for publication as both were successfully balloted (Part 1 in July 2007 and Part 2 Sept. 2008).

The NWIP for Phase II "Use Cases and Integration Profiles" (document N0702) was approved at the Rio meeting and has now been forwarded to ISO Central Secretariat.

Outcomes for Australia

Topic	Issue/Action/Recommendations	Owners
IHE Standards	<p>These are IHE documents that are being progressed to ISO Standards. In line with Australia's involvement with IHE, ballots in support of this Work Item should be considered.</p> <p>Action: Australia to consider the IHE Work Items as they progress through the ISO processes.</p>	IT-014 NEHTA

16.7 CLINICAL DOCUMENT REGISTRY FEDERATION (ISO 13128)

This work item originally put forward by Korea proposes a Technical Report that defines an extension to the IHE Document Registry in order to allow a federated registry/access model.

The new work item has now been approved by a ballot with sufficient subject matter experts having been named. The comments received during the ballot process are being incorporated into a revised draft of the Technical Report, which will be submitted to the May 2010 plenary

Work Item History and Progress at this Meeting

- This new work item had been approved by a ballot with sufficient subject matter experts having been named.
- The comments received during the ballot process were being incorporated into Draft Technical Report
- WG 2 had in Rio approved the "Draft Technical Report" provided Byoung-Kee Yi (South. Korea).
- The TR Ballot opened for ballot on 5 Aug. 2010 and closed on 5 Nov. 2010.

The Work Group agreed that the ballot resolution document will be processed at the Finland Plenary in May 2011.

Outcomes for Australia

Topic	Issue/Action/Recommendations	Owners
Clinical Document Registry Federation	<p>Although this document is also in the IHE domains, its relevance for Australia is not clear. IT-014 to seek input from stakeholders, in particular IHE Australia regarding this.</p> <p>Action: IT-014 to seek stakeholder input on the Australian response on the Clinical Document Registry Federation.</p>	IT-014 IHE Australia

16.8 QUALITY CRITERIA FOR SERVICES AND SYSTEMS IN TELEHEALTH (13131)

This Work Item seeks to define criteria for a process or the whole 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.

Work Item History

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).

At previous meetings, 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 has been changed to from "telemedicine" to "telehealth", with telemedicine being seen as a subset of telehealth.

A change in project leadership has caused delay.

Progress at this Meeting

From the Australian delegation, Anthony Meader (Chair IT-014-12) also attended this session.

Jan Talmon (The Netherlands) presented an update on 13131 including the topic of the scope definition of "Telemedicine" vs "Telehealth" (document N0719). He will survey experts to get more input into the discussion of scope, specifically on "Organisations and Actors" and "Definitions of Terms". Lee Sheldon (Malaysia) suggested that the draft be also exposed to other experts eg Alvin Marcelo (Philippines), OpenMRS, etc. which was agreed. The question of whether "Telelearning" should be kept in 13131 was also raised.

The Work Group agreed the following way forward:

- 2 weeks to modify text according to what is discussed today (1 Nov)
- 3 weeks for the expert group to comment (21 Nov)
- 1 week to revise (1 Dec)
- 4 weeks for comments to WG 2 (1 Jan)
- 2 weeks to revise and consult with expert group and put in ISO template
- Submit to CS for TS ballot by 15 Jan 2011

A resolution was proposed by WG 2 and passed by TC 215 to circulate the draft *"Quality Criteria for Services and Systems in Telehealth"* for ballot as an ISO Technical Specification, with the ballot draft expected to be ready in January 2011.

Outcomes for Australia

Topic	Issue/Action/Recommendations	Owners
Telehealth	<p>This item is potentially of high strategic importance to Australia, as it will define norms for operation of telehealth activities and may imply the scope for "acceptable" telehealth items within health agencies or for practitioners. Stronger engagement of Australia is desirable and should be discussed by IT-014.</p> <p>Action: IT-014 to consider stronger Australian engagement.</p>	<p>IT-014-12 IT-014</p>

16.9 DICOM WEB ACCESS TO DICOM PERSISTENT OBJECTS ("WADO")

This Work Item suggests that the original ISO 17432:2002 Web access to DICOM persistent objects (WADO) standard should be expanded with new web services enhancements.

Work Item History and Progress at this Meeting

At its October 2009 meeting, the Work Group decided that the new WADO web services should be added to the existing standard ISO 17432 as a revised version.

The Public Comment version of Supplement 148 (Refer document N0717) was put to WG 2 with emphasis on the items delineated in the closed and open issues lists.

Outcomes for Australia

Topic	Issue/Action/Recommendations	Owners
Web Services Access to DICOM Persistent Objects	While the DICOM standard is used in Australia, there are currently no formal local standards activities. Action: IT-014 (maybe through IHE Australia) to establish if there is a DICOM "Community of Interest" or any DICOM localisation needs.	IT-014 IHE Australia?

16.10 NEW BUSINESS ITEM: "MOBILE HEALTH"

Work Item Description

This new business item was brought forward by Il Kon Kim, Kyungpook National University of South.Korea (see document N0720). It seeks to address the issues around providing for Health Applications on Mobile/Smart Devices.

One particular health service may involve several family members with different mobile/smart devices: Smart phone, smart TV, smart eBook, etc.

A typical use-case would be a child who 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, it requires diverse services/capabilities such as displaying a graph of daily sugar levels and other relevant clinical documents/information, etc.

The question arises if the current standards are enough to support such health services.

Work Item Progress at this Meeting

The presentation elicited some discussion within WG 2 regarding use cases, scope and any possible overlap with other reference architecture.

The Work Group agreed to entertain a proposal for a Technical Report to investigate and analyse the need for reference architecture for smart devices in healthcare and proposed a resolution, passed by TC 215, to circulate the proposal for "Provisions for Health Applications on Mobile/Smart Devices" for ballot as an ISO Technical Report, with the draft copy for the report being expected to arrive at the TC 215 Secretariat by 20 November.

Outcomes for Australia

Topic	Issue/Action/Recommendations	Owners
Health Applications on Mobile/Smart Devices	This is forward-looking Work Item with its definition and implications not yet well-defined, but worth watching! Action: Australia to keep a watching brief how this Work Item develops.	IT-014

16.11 TERMINOLOGY BINDING TO MODELS

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 process of associating the precise set of codes to the coded element or datatype property is called "Vocabulary Binding". Vocabulary Binding may bind the coded element or datatype property to a single fixed value code or may bind it to a collection of codes.

Vocabulary binding is required to specify vocabulary conformance.

Work Item Progress at this Meeting

Ted Klein (from HL7) presented a report on Terminology Binding to Models (refer HL7 International web site:

www.hl7.org/v3ballot/html/infrastructure/coreprinciples/v3modelcoreprinciples.html#coreP_Coded_Binding

WG 2 agreed that a NWIP be created for Terminology Binding to Models.

Outcomes for Australia

Topic	Issue/Action/Recommendations	Owners
Terminology Binding to Models	As Australia actively uses both HL7 and its own terminology, this Work Item is relevant both to the HL7 Messaging (IT-014-06) and Terminology (IT-014-02) domains. Action: IT-014-02 and IT-014-06 to track this Work Item.	IT-014 IT-014-02 IT-014-06

16.12 FUTURE MEETINGS

The next meeting of WG 2 is planned to be held at HIMSS, 21-24 Feb. 2011, Orlando, USA. The next TC215 Full Meeting is in Kuopio, Finland, 23-27 May 2011.

It is not expected that breakout meetings of Special Working Group 2 (Architecture) and Special Working Group 3 (Methodology) will be scheduled at these two meetings.

The term of the Convenor, Michael Glickman, ends after the 2011 Plenary in Finland. At that time, WG 2 will hold elections.

17 WG 3 - SEMANTIC CONTENT

Australian Delegate Attendance	Heather Grain (WG3 Convenor) Others attended joint sessions with WG1/8
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Some 30 delegates attended WG 3, representing 13 countries (Australia, Brazil, Canada, China, Denmark, Finland, Germany, Japan, Korea, The Netherlands, Sweden, USA, UK) and one liaison (IHTSDO).

17.1 WORK ITEMS IN PROGRESS

The following work items are progressing as indicated.

1. ISO/NP TR12300 Mapping of terminologies to classifications

This work, led by Australia, is currently out to ballot. It is also the first trial of glossary harmonisation. The Secretariat sent the terminology clause of this document to each other members of the JIC along with ballot documents to gain their vote and comments on the proposed glossary duplication resolutions.

IT-014-02 is the Australian mirror group and has this item on its agenda as an ongoing issue for oversight and input.

2. JIC and the SKMT/Glossary project

The JIC accepted proposals put by Heather Grain to request each organisation to provide a contact person for communication of harmonisation ballots for glossary content.

There was demonstrable interest and many questions from the members of the JIC on how to participate. Written details will be provided to them.

3. Categorical Structures for anatomical structures (CatAnat – ISO/DTR 16278)

Combined comments from the NWIP ballot for work item CatAnat have been received with a particularly detailed and very supportive set of comments being received from IHTSDO. There are few current users of the work (UK have indicated that they are using the draft document on which the proposed TR is based). The comments will be disposed and a new version of the document will be made available at the next meeting.

4. System of concepts for the continuity of care (ContSys - EN13940 Parts 1 and 2)

This is a work item in two parts that was developed under the auspices of CEN/TC 251. Part 1 covers basic concepts and Part 2 covers health care process and workflow.

The two items are now out of sync and the solution to this is to withdraw the existing work items and create a new harmonised work item. This was accepted by the TC.

Action: NEHTA, IT-014-06 and IT-014-09 should consider how they wish to engage in this activity.

5. OID – Guidance for maintenance of object identifiers

This work is progressing with considerable activity taking place through the wiki and those interested in the topic are encouraged to visit the wiki site: <http://wiki.hl7.de/index.php?title=Hauptseite> (in German – follow the links, in English, to the relevant work items)

The next meeting expects a presentation of the first major draft to the OID work items which relate to the maintenance and access to registries of OIDs and the standardisation of those registries to support improved interoperability.

17.2 ISO/TS 17117 CRITERIA FOR THE CATEGORISATION AND EVALUATION OF TERMINOLOGICAL SYSTEMS

This work is a review of the existing Technical Specification, 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 are undertaking a detailed ontological review of the concepts of health terminology which is looking like a revolution and a very high quality piece of work. A draft is expected at the next meeting.

The work will clearly define the range of concepts to better define the relationships between classifications and terminological systems but has not yet come to agreement. The work targets an International Standard with the title: *"Health Informatics - Terminological resources"* - to be produced in three parts:

- Part 1 – Characteristics (focussed on definitions of terminology structured ontologically).
- Part 2 – Requirements
- Part 3 – Criteria for evaluation

Action: Recommendation that Australia support this NWIP and that IT-014-02 be given carriage of oversight of this for IT-014. The item is also of relevance to NEHTA

17.3 REVISION OF ISO 18104:2003 INTEGRATION OF A REFERENCE TERMINOLOGY MODEL FOR NURSING

Issues discussed related to the need to clarify specific concepts within this work item, as well as the title of the work item, for example:

- Category: a class or division of people or things regarded as having particular shared characteristics (Oxford English Dictionary)
- Possibility: inherent capacity for occurrence

Use cases have been requested to help test the options for the terminology model

The international nursing community have requested a change of name to: *"Categorical structures for representation of nursing diagnosis and nursing actions in terminological systems."*

This was the subject of some debate in both WG 3 and when the resulting resolution was put up at the mini-plenary. It was pointed out that in Australia the term nursing diagnosis is not used; this may require education of the nursing community and/or adaptation of the work to the Australian context when it is complete.

Action: IT14 members representing nursing organisations should be asked to contribute to the work on categorical structures for representation of nursing concepts.

17.4 CLAML – A SYNTAX TO REPRESENT THE CONTENT OF CLASSIFICATION SYSTEMS IN HEALTH CARE

This is a project based on upgrading the existing CEN TS 14463 technical specification to a full International Standard. The comments from the CD ballot which closed in July 2010 raised a number of issues and options: It is difficult to specify an adequate scope for the item as the classifications covered by the work item are difficult to define.

The concept of "generations of terminologies" is used in the document, but the associated provisions are based upon early work of Rossi Mori are no longer enough to cover the requirements. The option of delaying the work until the WG 3 work item on Terminological Resources – Characteristics is complete was not considered realistic when countries are seeking to use this work. Instead the document will include statements in the introduction to indicate that the characteristics of terminologies are evolving and examples of classifications which can safely use this work will be included in the document.

The heart of ClAML is a schema, currently provided as a document type definition (DTD), which has been superseded by contemporary XML-based technologies. The issue of how to represent the schema was discussed with 3 options presented:

- Continue as at present using a DTD
- Changed to an XML schema definition (XSD)
- Use a self-standing electronic document (as a DTD or XSD file).

It was agreed to continue with the DTD approach as this reduces vendor requirements to change from existing approaches, but that the option for XML or XSD files will be mentioned and be considered in the next review.

It was agreed that the comments will be addressed and the document will be ready to go out as a DIS by February 2011

18 TRADITIONAL MEDICINE

The Traditional Medicine Task Force (TMTF) met apart from WG3 for a half day. At the conclusion of this they returned to the WG for advice on their processes and work item proposals. WG3 serves as the mentor to the TM Taskforce. It was very clear that such oversight and support is still needed, as the processes and document content required some clarification, however the attendance at the meeting of a formal representative and liaison from China representing ISO/TC 219 Traditional Medicine was welcome and the meeting was constructive. This is an enormous step forward.

Two new work items were developed and presented. They are:

1. Acupuncture work items

New work item proposals have been prepared and were reviewed and improved by WG3 for a standard in two-parts.

- Categorical structures for representation of acupuncture – Part 1 – Acupuncture points
- Categorical structures for representation of acupuncture – Part 2 – Needling

These documents along with supporting documentation will be sent out to NP-ballot shortly.

Action: IT-014 needs to consider how we gain experts to contribute appropriately to these work items, and the priority of this work to Australia.

2. Traditional herbal medicine

Two work item proposals on herbal medicine were presented, one from Japan and one from Korea. WG3 advised that these work items need to be coordinated and structured to support other nationalities and cultures adding their requirements to this initiative. Suggested work item structure is:

- Traditional herbal medicine – Part 1 – General Principles
- Traditional herbal medicine – Part 2 – Japan
- Traditional herbal medicine – Part 3 – Korea

Draft new work item proposals for these work items will be prepared for consideration at the next meeting.

Representation of clinical findings in traditional medicine

Progress with the existing work item *ISO/DTS 6277-1 Categorical Structure for representation of clinical findings in traditional East Asian medicine – Part 1 – general principles* was reviewed and it was noted that the work is informing SNOMED CT and ICD communities.

A draft has not yet been prepared, but will be available for consideration at the next meeting of the TC in May 2011.

19 WG 4 - SECURITY, SAFETY AND PRIVACY

Australian Delegate Attendance	Limited coverage – mainly from joint sessions
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Some 25 delegates attended the various WG4 meetings representing 13 countries.

There has been on publication since the May 2010 meeting (passed up through WG 4 from the Health Card Task Force):

- *ISO 21549-8 Health informatics -- Patient healthcard data – Part 8 Links* (republished in July 2010)

The documents below were the focus of the WG 4's attention during the meeting:

- ISO DIS2 21091, Health informatics: Directory Services for healthcare providers, subjects of care and other entities

The changes from the DIS ballot were originally considered minor, but when accepted into the document, they resulted in technical changes of sufficient significance to require a further (DIS 2) ballot to confirm whether or not they are satisfactory. It is proposed to be a 2-month ballot.

A resolution from WG4 that the document goes to a second round DIS ballot was approved by TC215 in mini-plenary.

This work item has been a source of concern to some Australian experts who have implemented systems in the area and therefore warrants wider discussion.

- ISO Publication TS14265, "Classification of Purposes for processing personal health information"
- NWIP IS "Health informatics — Data Protection in trans-border flows of personal health information"
- ISO withdrawal of TS 25238, "Classification of Safety risks from health software"

- Systematic review of ISO TS 22600 Health informatics -- Privilege management and access control part 3:Implementation

The WG also received and discussed a report from the TC 215 delegation to the meeting of the ISO/TMB Privacy Steering Committee (PSC) held in Berlin in the week before the Rotterdam meeting. It appears that ISO is keen to coordinate activities in the area to address broader privacy protection issues in collaboration with privacy commissioners.

The WG also dealt with recommendations of the Health Cards TF in relation to the update, renewal and republication of various health card standards.

Action: The work of WG4 and associated sub-groups is relevant to Australia in moving forward on privacy and security issues associated with the PCEHR and with identification management in healthcare. Greater local engagement is sought.

19.1 ISO TS 14265 CLASSIFICATION OF DATA PURPOSES FOR PROCESSING OF PERSONAL HEALTH INFORMATION

This relatively simple standard aims to provide a uniform classification of proposed uses for personal health information to facilitate uniform automated interpretation of privacy/consent policies. Although simple, it is important that it is capable of being applied in conjunction with role identification and access control standards to fulfil proposed needs. The document had been circulated and passed DTS ballot (15 in favour, 1 against, 9 abstentions, 4 did not vote) and attracted a total of 27 comments.

The standard proposes 14 classes of purpose.

Prof. Kalra and Ms. Sawatsky discussed issues arising from the ballot response. There was considerable discussion, which focussed on purposes needed for financing of care provision to an individual subject of care. A change in terminology from financing to funding was suggested, to more clearly include public and private health systems. The following matters were covered in discussion:

- Several delegates were unhappy with the use of word 'funding', since it was not the same as 'financing'. Mr. Dixon-Hughes suggested 'payment for care provision' as a possible alternative.
- The proposed categories (point 5 in the presentation) were accepted without further comment.
- There were discussions on the legal procedure (point 12 in the presentation). Legal proceeding would have another meaning in Canada - a law process.
- Point 13 in the presentation was accepted without further comments.
- Mapping to Swedish categories of purpose was discussed at some length with Mr. Dixon-Hughes noting that it was a particularly interesting piece of work.
- Concern was expressed from Germany about this work item, and preferred a solution in the context of ISO TR 22600 (PMAC) using a more versatile policy model.
- Proposal for agreement:
 - prepare disposition and updated draft by end of October
 - circulate to experts for two weeks
 - if accepted circulate to WG 1, 4 and 8 for four weeks
 - if accepted proceed to publication

19.2 OUTCOMES FOR AUSTRALIA

Over time, Australia has contributed significantly to the work of WG4, providing the initial drafts of ISO 27799:2008 - Security management in health using ISO/IEC 27002, and contributing expert input and critical comment during development of:

- ISO/TS 22600 Privilege management and access control (PMAC)
- ISO/TS 21298 Functional & structural roles;
- ISO/TS 13606-4 EHR communication – Part 4: Security
- ISO/TS 23257 Pseudonymisation

Privacy and security are essential components of the Australian eHealth program but greater engagement of relevant experts and affected parties is required to progress the local work of IT-04-04, potential adoption of relevant TC 215/WG4 standards in Australia and feedback of local experience as WG4 reviews ISO technical specifications for upgrade to full international standards.

20 WG 6 - PHARMACY AND MEDICATION BUSINESS

Australian Delegate Attendance	Limited coverage of key issues - Evelyn Hovenga
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The various WG 6 sessions at this meeting were well attended.

For several years, WG6 activities have been dominated by two major pieces of joint ISO/CEN work – the Identification of Medicinal Products (IDMP) and the Individual Case Safety Report (ICSR) series of standards. The pharmaceutical industry, regulators and informaticians are all involved in the work, with much of the time at meetings being spent in detailed work on these documents; however, there is now interest in progressing further items as these near completion.

The following progress was noted:

ISO/FDIS 27953 Pharmacovigilance - Individual case safety report (ICSR)

This standard comprises two parts:

- Part 1: The framework for adverse event reporting
- Part 2: Human pharmaceutical reporting requirements for ICSR

These parts both passed their second-round DIS ballot in September and were approved by TC 215 for a final joint ISO/CEN FDIS ballot in February, hopefully resulting in publication as full international standards around mid-year.

IDMP series of standards

There are five main normative standards in the IDMP (Identification of medicinal products) suite, covering data elements and structures for the unique identification and exchange of: - regulated medicinal product information (11615); regulated pharmaceutical product information (11616); regulated information on substances (11238); regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging (11239); and Units of Measurement (11240).

All are currently out for 5-month DIS ballot closing on 23 February 2011, so there was little for WG 6 to do on them at the October meeting.

To assist users in the implementation of the IDMP series of standards, WG 6 has prepared: *ISO 14872 Health informatics – Requirements for the implementation of the standards for the identification of medicinal products for the exchange of regulated medicinal product information*.

In mini-plenary, TC 215 approved this being released for DTR ballot and is expected in December.

ISO/TS 10895 Health informatics – Business requirements for pharmacy professional services messages

Mr. Nigel Cox (UK) is the lead on this project, which passed NP ballot in 2007 but has not progressed – with no further recent input from the expert group. Potential links with WG 3 categorial structure standards were noted and also the Pharmacy Provider EHR specifications being produced in the US [possibly related to NCPDP and/or the HL7 EHR-S FM]. It was concluded that these potential relationships should be followed up and that the project continued to have value if it could inform WG 6 of these developments.

20.1 TR 25257 BUSINESS REQUIREMENTS FOR AN INTERNATIONAL MACHINE-READABLE CODING SYSTEM FOR MEDICINAL PRODUCTS

At its previous meeting in May 2010, WG6 had proposed that *TR 25257 - Business Requirements for an international coding system for medicinal products*, which was published in August 2009 (with lead: Ock-Hee Oh of South Korea) be reviewed and updated on the grounds.

- Parts had been superseded by recent legal changes in several jurisdictions
- Aspects needed to be harmonised with emerging IDMP work, and
- Developing work within GS1 should monitored

The revision was being promoted by GS1 as a potential new JIC work item and it was previously agreed that Australia should support this proposal being progressed. It will enable closer engagement with GS1 by NEHTA.

Christian Hay of GS1 has been elected the project lead for the update which was put to NP ballot and failed due to insufficient experts being nominated. The following decisions have been taken by WG 6 to progress the item:

- A new document will be produced instead of the proposed revision of the existing ISO/TR 25257.
- Consideration was given as to whether the document should be a TR or TS with WG 6's proposal to ballot it as a NWIP for a TS being accepted by TC 215 in mini-plenary.
- HL7 pointed out that the new document should be based on best practices, which may come from GS1 projects which predominate in this domain.
- There are countries which have successfully implemented a bar coding system of which general principles can be described in a technical specification
- The following countries committed to support the NWIP: UK (Nigel Cox), USA (LuAnn Whittenburg), Canada (Gary Cruickshank), Netherlands (Frits Elferink), Germany (Thomas Baltzer). Mr. Hay (GS1) will continue leading this NWIP.

Action: In conjunction with the GS1 session at the January 2011 WGM, Australia attempt to find an appropriate expert to participate in the work on an international coding system for medicinal products.

20.2 GENERIC MODEL FOR DOSE SYNTAX

An update on this preliminary work item was given by Ms. Jo Goulding, Head of Pharmacy Terminology at the UK NHS, who is also active in the SNOMED CT community.

- The chair informed WG6 that this subject is very important in the UK which supports the exchange of reliable dosing information between systems and between healthcare providers. NHS has signified that it is committing resources to this project.
- As presented in the May 2010 meeting, this potential work item will build on the 2008 Implementation Guidance for the NHS Dose Syntax and other experiences, such as those from HL7.
- An issue was raised as to which WG was appropriate for the work item; TC 215/WG 1 or 6. Although the title contains "model" the subject is not about modelling – but more about business processes.
- The scope is to describe the business requirements in clinical domain to assure patient safety. The model is not the main result of the work item, but will support the business requirements. At the moment, the current document focuses more on the modelling than patient safety.
- Procedurally, the JIC has embraced this topic and approved the work item as JIC WI. Furthermore, ISO/TC 215 has been appointed as lead SDO. Finally, the development of the work item needs to be designated to a WG within ISO/TC 215.
- As the scope focus will differ from modelling to clinical business requirements, WG6 is perceived as the natural home for this work item. Dr. Leao did point out that WG8 is working on several EHR models so there is need for future joint sessions to inform the other WGs. This was agreed.
- It was decided to amend the title and scope in form 4 to capture all discussions and agreed recommendations.

On the recommendation of WG 6, TC 215 approved the NWIP for "*Business requirements for a syntax to exchange structured dose information for medicinal products*" being circulated for ballot targeting the development of a technical specification.

21 WG 7 – DEVICES

Australian Delegate Attendance	Limited coverage of key issues: - Anthony Maeder - Richard Dixon Hughes
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Principal Australian involvement with WG7 was in joint sessions with WG1 (re DCM), WG2 (re telehealth), WG1/3/8 (re CDSS and alerts).

WG7 has a long history of working closely with medical device standards being progressed by HL7, IEEE and IEC – with much of the joint development being done in these other SDOs and then adopted as international standards through TC 215.

A major focus is WG7 contributing experts to joint work on the IEC/ISO 80001 standards on "risk management for IT-networks incorporating medical devices" being produced by the IEC SC62A/JWG 7

group in active collaboration with TC 215/WG7 and IEEE. These standards are focussed on safety and have the potential to impact a wide range of equipment used in health care settings. They are being progressed through meetings held about 4 to 6 times per year in conjunction with meetings of the parent SDOs.

This group is not specifically monitored by Australia. Its final recommendation was to present a Preliminary New Work Items for International Standards on the following IEEE 11073 projects:

- 11073-10419 Health informatics - Personal health device communication- Device specialization - Insulin pump
- 11073-10420 Health informatics - Personal health device communication - Device specialization - Body composition analyzer
- 11073-10421 Health informatics - Personal health device communication - Device specialization - Peak expiratory flow monitor (peak flow)
- 11073-10418 Health informatics - Personal health device communication - Device specialization - INR analyzer
- 11073-10413 Health informatics - Personal health device communication- Device specialization - Respiration rate
- 11073-10443 Health informatics - Personal health device communication- Device specialization - Physical activity monitor

Specific points noted by Prof Maeder included:

- There are incompatibilities between Continue specifications for use in some health devices and industry-standard approaches (e.g. Bluetooth)
- There are long-term difficulties overcoming legacy situations and replacing vendor formats with uptake of open consensus standards in areas such as ECG
- There is a lot happening on IEEE 11073 but it would seem difficult to have good input to review/development of these standards from Australia because they are being driven by US-based IEEE committees.
- There is a problem promoting lower-consensus IEEE documents into ISO – the partner agreement typically used for 11073 documents only applies to full standards and not TS- and TR-level specifications.

22 WG 8 - BUSINESS REQUIREMENTS FOR EHR

Australian Delegate Attendance	Richard Dixon Hughes, Heather Leslie, Evelyn Hovenga Andrew Caswell (WG8 Secretariat) Occasional attendees: - Heather Grain, Anthony Maeder
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Most of the WG8 program was held jointly with WG1 (Data Content) and with CEN/TC 251/WG I with the chair alternating between convenors.

Some 70 delegates attended, representing at least 19 countries and at least 2 liaisons (WHO & HL7)

ISO/CD 13972 Detailed clinical models

There has been considerable local interest and some controversy over the work on *ISO/CD 13972 Detailed clinical models*. This project was discussed in a dedicated meeting of the project team as well as in presentations to WG 1 and WG 8 and to the JIC Harmonisation Track. Given the breadth of this topic and the level of Australian engagement an interest, it is separately reported in [section 15 above](#).

22.1 ISO TR 14639 E-HEALTH ENTERPRISE ARCHITECTURE

ISO TR 14639 eHealth enterprise architecture for emerging and developing countries is proposed technical report in two parts:

- Part 1: Environmental Scan; with leads: Beatriz Leao – BR, Patrick Whitaker – WHO
- Part 2: Business Requirements; with leads: Beatriz Leao – BR, Patrick Whitaker – WHO

Richard Dixon Hughes of Australia is one of the principal authors of the work to date, with other significant with a significant Australian contribution being made by Dr Anthony Maeder of UWS and earlier input from Ken Tallis at the AIHW.

In joint session with WG 1 hosted by WG 8, Dr. Leao presented the status of this project, which included the timeline and the issues faced by the project group.

- There was considerable discussion of the title of the work item – particularly avoiding the words “emerging and developing”. A smaller group workshopped possible changes for some time during the preparation of resolutions, leading to WG 8 recommending that the title of the work item be changed to:
 - *ISO 14639-1 HI - Capacity-based e-health architecture roadmap - Part 1: Overview of national e-health initiatives; and*
 - *ISO 14639-2 HI – Capacity-based e-health architecture roadmap - Part 2: Architectural components and maturity model.*

The recommendations were accepted by TC 215 in plenary.

- Many questioned whether the intention of the work was to establish a new e-health architecture – to which the answer was a very definite ‘no’ – the work is to elaborate on the components that needed to be included in various types of eHealth architectures – for different levels of requirement from developing and emerging countries through to those with an advanced health system.
- It was agreed that WG1 and WG8 experts would be given a six week informal review period before Part 1 is circulated for DTR ballot. The ballot is expected to commence in February.

22.2 ISO/DTR 14292 PERSONAL HEALTH RECORDS: DEFINITION, SCOPE AND CONTEXT

This work being led by Dipak Kalra (UK) with assistance from Gora Datta (USA) and is aimed at a technical report that seeks to provide a researched definition and framework for work on the personal health record (PHR) – similar to earlier work (led by Australia) that led to ISO/TR 20514 on EHR definition, scope and context. The work aims to:

- provide a definition of the personal health record
- describe the classification of personal health records

- describe the ways in which the inclusion and engagement of individuals in managing their health and health care impacts on the roles of the personal health record, and
- illustrate this through case study examples.

Dipak Kalra and Gora Datta provided an update on progress, with the following being noted:

- Key revisions have been incorporated since discussion at the May meeting and provision of additional material;
- Additional small but relevant changes were proposed to the definition of a PHR – notably removal of the word “logical” (logical representation of information);
- The proposed use-case annex was removed due to insufficient cases being submitted by WG members; however, the use cases have been replaced by links to relevant PHR sites; and

A proposed resolution from WG 8 that ISO 14292 *HI – Personal health records - definition, scope and context* be issued for DTR ballot was approved by TC 215 in mini-plenary with the associated ballot documentation expected to be issued in November.

Action: IT-014-09 to prepare ballot response

22.3 DTR 13054: STANDARDS KNOWLEDGE MANAGEMENT

Dr. Andrew Grant (Sherbrooke University, Canada) provided an update on the status of the project, including a demonstration of SKMT as part of an integrated standards knowledge management ecosystem being tested with the ISO TR 14649.

It was agreed that there would be a six week informal review period by the ISO-215 experts and then the ISO/TC215 Secretariat would circulate the DTR ballot of ISO 13054 “*HI – Knowledge management of health information standards*” for approval as a Technical Report.

22.4 ISO FDIS 18308

Prof. Dipak Kalra presented the status of the project to upgrade ISO/TS 18308 to a full international standard, which is now approaching the final FDIS ballot.

- The project passed its DIS2 ballot.
- Various changes to clarify statements had been made, plus incorporation of contributions from Ms. Sawatsky and Mr. Ritz on privacy and security.
- There had been a complete redrafting focussing on harmonisation with the HL7 EHR-S Functional Model and other relevant standards.
- The revised text was submitted to ISO CS in August with the expectation of an FDIS ballot commencing in early Jan 2011.
- The project delay was mainly attributable to the option of a full French translations being exercised.

22.5 ISO NWIP 16527 PHR-S FUNCTIONAL MODEL V1.0

Dr. Don Mon (HL7 and WG 1 Vice-convenor) presented the status update for the project, noting that:

- Passed NWIP ballot in October with 17 countries voting in favour, 8 abstaining and none voting against. Experts had been proposed from AU, FI, DE, JP NE and US.

- 48 pages of comment had been received from Canada, Sweden and the UK – with the vast bulk from Canada.

He was unwilling to commit to a timeframe, but, equally, was not seeking a formal resolution from this meeting.

It is noted that progression in ISO is likely to be linked to progression of the underlying work in HL7.

The next step will be to proceed to DIS ballot once all revisions to the HL7 PHR-S FM DSTU have been made.

22.6 OTHER TOPICS

- A Joint meeting of WG 1 with WG*8 and WG 6 in the area of *"Requirements, frameworks and architectures"* was hosted by WG 8, which addressed the following work items reported in section 20 above (WG 6 Medications and Pharmacy Business):
 - IDMP Update (Mr. Ian Shepherd) - all 5 standards are in DIS ballot until 23 February 2011.
 - Proposed Generic model for dose syntax
- *"The use of standards in Brazil"* – presented in joint session with WG 1 (see section 14.1 above)
- *Framework for National Information Systems (NWIP ISO/TS 16555)*. This WG 8 project was originally proposed by WHO and passed NP ballot in October with next steps being discussed in joint session with WG 1 (see section 14.1 above).
- *ISO 14199 BRIDG Domain analysis model for protocol drive biomedical research*. See section 16.2 above.
- *ISO 21667: Health indicators conceptual framework* - finally published on 26 Nov 2010.
- *ISO 10781: EHR System Functional Model - Release 2*.

Dr. Donald Mon provided an update to WG 1 and WG 8 on developments in bringing this substantial piece of work on the JIC joint work program to ballot in HL7 and ISO.

- He indicated that he did not initially believe that an NWIP was required, but now accepts that it is.
- The work was progressing well with weekly or fortnightly conference calls as the main medium of communication.
- More input was solicited from the ISO participants.

23 PATIENT SAFETY AND QUALITY TASK FORCE (PSQ-TF)

Australian Delegate Attendance	Anthony Maeder
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Noting growing world-wide emphasis on patient safety and quality of care (PSQC), this task force had planned to produce a technical report on how TC 215 can support PSQC through its standardization activities. Having reviewed the field and produced a background report, the PSQC concluded:

- Further discussion regarding consideration of publishing a technical report summarizing the assessment and review of the task force be deferred

- It recommend to the TC 215 Organisation Task Force that there be a TC215 group that would address standardization supporting Patient Safety and Quality
- It recommend there be standards produced from TC215 in Patient Safety and Quality to address the gaps identified by PSQC in its report on the subject
- To recommend that the work of the PSQ TF be carried on by a WG dedicated to Patient Safety and Quality or one that deals with this and other aspects of clinical care applications. This WG would continue with the prioritization of the work recommended by the TF.
- The scope for TC 215 work in the PSQ field should be:

The harmonization, adaptation or, where necessary, development of health informatics standards that:

- *provide methodologies to minimize errors in the collection, processing, use or disclosure of health information;*
 - *enable and support the implementation of best practices in clinical care by means of healthcare information technology; and*
 - *provide systematic support for health systems oversight with respect to patient safety and quality of care.*
- National Member Bodies should be encouraged to reach out to experts in Patient Safety and Quality to build out the TC215 expertise in this area, and that the outreach to experts be extended to the following Patient Safety and Quality initiatives to engage liaisons:

Outcomes for Australia

Circulation of the PSQ TF's report and findings is an opportunity for IT-014 to engage with the ACSQHC and other groups interested in PSQC.

Australia noted that there needs to be convergence and/or reconciliation of the definitions of quality used in various TC 215 work items (eg.13131 Quality Criteria for Telehealth).

24 TC 215 OPENING MINI-PLenary

Australian Delegate Attendance	Richard Dixon Hughes (Head of Delegation) Heather Grain (WG 3 convener) Andrew Caswell (WG 8 secretariat) Anthony Maeder, Evelyn Hovenga, Heather Leslie
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The opening plenary is largely a formality at which the following business was transacted:

1. Opening of the meeting – Welcome by ISO/TC 215 Chair, Dr. Chris Chute
2. Welcoming Remarks and introduction of official speaker – by Dr William Goossen, Head of Delegation for The Netherlands.
3. Official welcome to the Rotterdam meeting on behalf of the Ministry of Health, Welfare and Sport in The Netherlands (MHWS).

The welcome was delivered by Ms Ellen Maat, Program Director, Innovation and ICT in the MHWS. Ms Maat indicated that the Netherlands is having significant debates over privacy and security of health information, recognising both the emotional and rational elements to that debate. They encounter many wrong assumptions and misunderstandings, which are indicative of similar issues in many countries. There is formal Parliamentary recognition that standards are a precondition for delivering good health IT. She also raised the world-wide problem posed by the growing demand for healthcare, the growth of the sector and consequent difficulties of meeting the demand for skilled health workers. The Netherlands will need more than 500,000 extra staff to care for the elderly under current care paradigms. Like Australia they are looking to IT as one of the mechanisms to support change in health care delivery.

4. Organisational announcements

25 TC 215 CLOSING MINI-PLenary

Australian Delegate Attendance	Richard Dixon Hughes (Head of Delegation) Heather Grain (WG 3 convener) Andrew Caswell (WG 8 secretariat) Evelyn Hovenga Heather Leslie Anthony Maeder Klaus Veil
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The closing plenary addressed the following agenda, with all working group resolutions being separately recorded in section 26 below along with the Australian delegation's understanding of the likely actions to ensue.

1. Opening of meeting by Dr. Chute, Chair of ISO/TC 215
3. Recognition of liaisons who participated in the meeting: CDISC, GS1, IHTSDO, WHO, ICH, IHE, JTC1 and TC 210 [Richard Dixon Hughes –AU ISO/IEC liaison officer to TC 215]
4. Roll Call of ISO/TC 215 Participating Member Delegates.
5. Adoption of agenda
6. ISO/TC 215 Chair and Executive Council report.

7. Resolutions from the Working Groups. The convener of each working group then gave a brief PowerPoint presentation on their group's activity and led voting on the resolutions put forward by her/his working group. The more significant material covered in these presentations has been covered in the working group reports above and the resolutions are reported in full in sections recorded in section 26 below.

26 RESOLUTIONS FROM TC 215 MINI-PLenary

Resolutions for the mini- plenary are drafted by the working groups, task forces and other constituent bodies within TC 215 and must 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 mini-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 mini-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.

26.1 RESOLUTIONS APPROVED

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

Resolution	Further action	By
1. Resolved that ISO/TC215 accepts the report of the Executive Council.	Chair's verbal summary to be minuted	TC215 Secretariat
2. Resolved that ISO/TC 215 accepts the report of ISO/TC 215 WG 1.	Summary presentation by WG convenor available with minutes	WG Convenor TC 215 Secretariat
3. Resolved that ISO/TC215 approves the WG1 recommendation that the ISO/TC215 approve the split of the draft document prEN ISO 13972 " <i>Health informatics - Quality requirements and methodology</i> " into part 1: prEN ISO 13972-1 " <i>Health Informatics - Quality processes regarding detailed clinical model development, governance, publishing and maintenance</i> " and part 2: prEN ISO 13972-2 " <i>Health informatics - Quality attributes of detailed clinical models</i> ".	Split of work item	TC 215 Secretariat
4. Resolved that ISO/TC215 approves the WG1 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of " <i>Health informatics - EHR clinical research functional profile</i> " for approval as a new work item targeting IS via the Vienna Agreement with CEN lead and the Form 4 and a document arrives at the TC Secretariat no later than 1 December 2010 to be placed on the ISO/TC 215 balloting portal no later than 15 December 2010.		AU: IT-014 to decide approach for responding to this ballot Also see res 6, 9
5. Resolved that ISO/TC 215 accepts the report of ISO/TC 215 WG 2.	Summary presentation by WG convenor available with minutes	WG Convenor TC 215 Secretariat

Resolution	Further action	By
6. Resolved that ISO/TC215 approves the WG 2 recommendation that the ISO/TC215 Secretariat circulate the NWIP ballot of <i>“HI: Clinical Trials Registration & Reporting”</i> for approval as a new work item targeting a IS and that the Form 4 and a document arrives at the TC Secretariat no later than 2010-10-22 be placed on the ISO/TC web site no later than 2010-11-05.		AU: IT-014 to decide approach for responding to this ballot Also see res 9
7. Resolved that ISO/TC215 approves the WG 2 recommendation that the ISO/TC215 Secretariat approve the project to define a procedure for updating the <i>“HL7 V3 Reference Information Model - Maintenance Release Process”</i> . The procedure to be advanced at the next plenary with the goal of authorizing a committee internal ballot.		AU: IT-014-06 IT-014-09 for ballot response
8. Resolved that ISO/TC215 approves the WG 2 recommendation that the ISO/TC215 Secretariat circulate the DTS ballot of ISO# 13131 <i>“HI: Quality Criteria for Services and Systems in Telehealth”</i> for ballot and that the document arrives at the TC Secretariat no later than 2011-01-15 and be placed on the ISO/TC web site no later than 2011-01-29.		AU: IT-014-12 for ballot response
9. Resolved that ISO/TC215 approves the WG 2 recommendation that the ISO/TC215 Secretariat forward CD 14199 <i>“The BRIDG domain analysis model for protocol-driven biomedical research, V3.0.2”</i> to the ISO Central Secretariat for circulation as a DIS ballot. A revised document, separate revisable figure files and a completed table of comments will arrive at the TC secretariat no later than 2010-11-20.		AU: IT-014 to decide approach for responding to this ballot Also see res 6
10. Resolved that ISO/TC215 approves the WG 2 recommendation that the ISO/TC215 Secretariat circulate the NWIP ballot of <i>“HI: Provisions for Health Applications on Mobile/Smart Devices”</i> for approval as a new work item targeting a technical report and that the Form 4 and a document arrives at the TC Secretariat no later than 2010-11-20 and be placed on the ISO/TC web site no later than 2010-12-04.		AU: IT-014-06, IT-014-012 for ballot response
11. Resolved that ISO/TC 215 accepts the report of ISO/TC 215 WG 3.	Summary presentation by WG convenor available with minutes	WG Convenor TC 215 Secretariat
12. Resolved that ISO/TC215 approves the WG 3 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of <i>“Health informatics Structure and maintenance of the health informatics glossary”</i> for approval as a new work item targeting a TS and that the Form 4 and a document arrives at the TC Secretariat no later than 15 January 2011 to be placed on the ISO/TC 215 balloting portal no later than 30 January 2011.		AU: IT-014-02 for ballot response

Resolution	Further action	By
13. Resolved that ISO/TC215 approves the WG 3 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of <i>“Health informatics - Terminological resources – Part 1: Characteristics,”</i> for approval as a new work item targeting an IS and that the Form 4 and a document arrives at the TC Secretariat no later than 15 January 2011 to be placed on the ISO/TC 215 balloting portal no later than 30 January 2011.		AU: IT-014-02 for ballot response NEHTA TS for comment
14. Resolved that ISO/TC215 approves the WG 3 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of <i>“Health informatics - Categorical structures for the representation of acupuncture – Part 1 – Acupuncture points”</i> for approval as a new work item targeting a TS and that the Form 4 and a document arrives at the TC Secretariat no later than 31 October 2010 to be placed on the ISO/TC 215 balloting portal no later than 15 November 2010.		AU: IT-014-02 for ballot response
15. Resolved that ISO/TC215 approves the WG 3 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of <i>“Health informatics – Categorical structures for the representation of acupuncture – Part 2 -Needling”</i> for approval as a new work item targeting a TS and that the Form 4 and a document arrives at the TC Secretariat no later than 31 October 2010 to be placed on the ISO/TC 215 balloting portal no later than 15 November 2010.		AU: IT-014-02 for ballot response
16. Resolved that ISO/TC215 approves the WG 3 recommendation that the work item ISO 18104 <i>“Health informatics – Integration of a reference terminology model for nursing”</i> be renamed <i>“Health informatics – Categorical structures for representation of nursing diagnoses and nursing actions in terminological systems”</i>	Renaming of work item	TC 215 Secretariat
17. Resolved that ISO/TC215 approves the WG 3 recommendation that the ISO/TC215 Secretariat circulates ISO 18104 <i>“Health informatics – Categorical structures for representation of nursing diagnoses and nursing actions in terminological systems”</i> as a 3 month CD and a document arrives at the TC Secretariat no later than 15 January 2011 to be placed on the ISO/TC web site no later than 30 January 2011.		AU: IT-014-02 for ballot response
18. Resolved that ISO/TC215 approves the WG 3 recommendation that the ISO/TC215 Secretariat forward prEN ISO 13120 <i>“Health informatics – A syntax to represent the content of classification systems in health care”</i> to the ISO Central Secretariat for circulation as a DIS ballot via the Vienna Agreement with ISO lead. A revised document, separate revisable figure files and a completed table of comments will arrive at the TC secretariat no later than 20 January 2011.		AU: IT-014-02 for ballot response AIHW and NEHTA TS for comment

Resolution	Further action	By
19. Resolved that ISO/TC215 approves the WG 3 recommendation that the ISO/TC215 Secretariat forward prEN ISO 1828 <i>“Health informatics – Categorial structure for terminological systems of surgical procedures”</i> to the ISO Central Secretariat for circulation as a DIS ballot via the Vienna Agreement with ISO lead. A revised document, separate revisable figure files and a completed table of comments will arrive at the TC secretariat no later than 31 October 2010.		AU: IT-014-02 for ballot response AIHW and NEHTA TS for comment
20. Resolved that ISO/TC215 approves the WG3 recommendation that prEN ISO 13940-1 <i>“Health informatics – System of concepts to support continuity of care – Part 1 – Basic concepts”</i> be withdrawn from the ISO/TC215 program of work.	Removal of work item	TC 215 Secretariat IT-014 to note
21. Resolved that ISO/TC215 approves the WG3 recommendation that prEN ISO 13940-2 <i>“Health informatics – System of concepts to support continuity of care – Part 2 – Core processes and workflow in healthcare”</i> be withdrawn from the ISO/TC215 program of work.	Removal of work item	TC 215 Secretariat IT-014 to note
22. Resolved that ISO/TC215 approves the WG 3 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of prEN ISO 13940 - <i>“Health informatics –System of concepts to support continuity of care”</i> for approval as a new work item targeting an IS via the Vienna Agreement with ISO lead and the Form 4 and a document arrives at the TC Secretariat no later than 31 October 2010 to be placed on the ISO/TC 215 balloting portal no later than 15 November 2010.		AU: IT-014 to note AU: IT-014-02 for ballot response
23. Resolved that ISO/TC 215 approves the WG3 recommendation that the ISO/TC 215 Secretariat accepted an active working liaison with Olivier Debuissou, of ITU-T SG17, related to the joint work on the WG3 work items: ISO/NP 13581: <i>Health informatics – Guidance for maintenance of object identifiers</i> , and ISO/NP 13582: <i>Health informatics – Communication model and XML interface specification for OID registries</i> .	Arrangement of liaison	TC 215 Secretariat JTC1 Liaison (RDH) to follow-up
24. Resolved that ISO/TC 215 accepts the report of ISO/TC 215 WG 4.	Summary presentation by WG convenor available with minutes	WG Convenor TC 215 Secretariat
25. Resolved that ISO/TC215 approves the WG4 recommendation that the ISO/TC215 Secretariat forward ISO 21091, <i>“Health informatics: Directory Services for healthcare providers, subjects of care and other entities”</i> to the ISO Central Secretariat for circulation as a 2nd DIS ballot. A revised document with separate revisable figure files and a completed table of comments will arrive at the TC secretariat no later than January 30, 2010		AU: IT-014 for ballot response Of general AU interest – seek community comment

Resolution	Further action	By
26. Resolved that ISO/TC215 approves the WG4 recommendation that the ISO/TC215 Secretariat forward ISO TS14265, " <i>Classification of Purposes for processing personal health information</i> " to the ISO Central Secretariat for publication, and that the document arrives at the TC Secretariat no later than October 22, 2010.		AU: IT-014, IT-014-04, IT-014-09, IT-014-02 for ballot response Of general interest – seek community comment
27. Resolved that ISO/TC215 approves the WG4 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot, " <i>Health informatics — Data Protection in trans-border flows of personal health information</i> " for approval as a new work item targeting an International Standard via the Vienna Agreement with an ISO lead and the Form 4 and the document arrives at the TC Secretariat no later than October 20, 2010 to be placed on the ISO/TC 215 balloting portal no later than November 3, 2010.		AU: IT-014,, IT-014-04, IT-014-09, IT-014-02 for ballot response Of general interest – seek community comment
28. Resolved that ISO/TC215 approves the WG4 recommendation that the ISO/TC215 Secretariat circulates ISO 20301, " <i>Health Informatics – Health Cards – General Characteristics</i> " as a 2 month CD and a document arrives at the TC Secretariat no later than October 20, 2010 to be placed on the ISO/TC web site no later than November 3, 2010.		AU: Expected to abstain
29. Resolved that ISO/TC 215 approves the WG4 recommendation that the ISO/TC 215 Secretariat to forward to ISO 21549-1 <i>Patient Health Card Data Part 1 General Structure</i> for ISO Central Secretariat to confirm with editorial corrections, and that the document arrives at the TC secretariat no later than October 20, 2010.		AU: Expected to abstain
30. Resolved that ISO/TC215 approves the WG4 recommendation that the ISO/TC215 Secretariat forward DIS 21549-2 " <i>Patient Health Card Data Part 2 Common Objects</i> " to the ISO Central Secretariat for circulation as a 2 month CD ballot. A revised document, separate revisable figure files and a completed table of comments will arrive at the TC secretariat no later than October 20, 2010.		AU: Expected to abstain
31. Resolved that ISO/TC215 approves the WG4 recommendation that the ISO/TC215 Secretariat forward DIS 21549-3, " <i>Patient Health Card Data Part 3 Limited Clinical Data</i> " to the ISO Central Secretariat for circulation as a 2 month CD ballot. A revised document, separate revisable figure files and a completed table of comments will arrive at the TC secretariat no later than October 20, 2010.		AU: Expected to abstain
32. Resolved that ISO/TC215 approves the WG4 recommendation that the ISO/TC215 Secretariat forward DIS 21549-4, " <i>Health Cards – General Characteristics</i> " to the ISO Central Secretariat for circulation as a 2 month CD ballot. A revised document, separate revisable figure files and a completed table of comments will arrive at the TC secretariat no later than October 20, 2010.		AU: Expected to abstain

Resolution	Further action	By
33. Resolved that ISO/TC215 approves the WG4 recommendation that TS 25238, " <i>Classification of Safety risks from health software</i> " to be revised and support the intent to withdraw the standard once a new standard is available from the ISO/TC215 program of work.		AU: IT-014 to note
34. Resolved that ISO/TC215 approves the WG4 recommendation that <i>Health informatics -- Privilege management and access control part 3 Implementations</i> be brought forward for systematic review at the earliest time so that the review of parts 1 Overview and Policy Management and 2 Formal Models of TS22600, " <i>Health informatics -- Privilege management and access control</i> " can be managed efficiently.		AU: IT-014 to note especially IT-014-04 and IT-014-09.
35. Resolved that ISO/TC215 approves the WG4 recommendation that ISO/TC 215 WG4 support the work to leverage Standards Knowledge Management Tool of ISO TC 215 for the ISO/TMB Privacy Steering Committee 01.		AU: IT-014 to note
36. Resolved that ISO/TC 215 accepts the report of ISO/TC 215 WG 6.	Summary presentation by WG convenor available with minutes	WG Convenor TC 215 Secretariat
37. Resolved that ISO/TC215 approves the WG 6 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of ISO 25257, " <i>Health informatics – Requirements for international machine-readable coding of medicinal product package identifiers</i> " for approval as a new work item targeting a Technical Specification and that the Form 4 and a document arrives at the TC Secretariat no later than 1 November 2010 to be placed on the ISO/TC 215 balloting portal no later than 15 November 2010		AU: IT-014 to consider engagement strategy involving IT-014-02 IT-014-06-04 Supply chain
38. Resolved that ISO/TC215 approves the WG 6 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of " <i>Health informatics – Business requirements for a syntax to exchange structured dose information for medicinal products</i> ", for approval as a new work item targeting Technical Specification via the Vienna Agreement with ISO lead and the Form 4 and a document arrives at the TC Secretariat no later than 1 November 2010 to be placed on the ISO/TC 215 balloting portal no later than 15 November 2010.		AU: IT-014 to consider engagement strategy involving IT-014-02 IT-014-06-04 NEHTA (AMT)
39. Resolved that ISO/TC215 approves the WG 6 recommendation that the ISO/TC215 Secretariat forward prEN ISO 27953-1 " <i>Health informatics – Pharmacovigilance – Individual case safety report – Part 1: The framework for adverse event reporting</i> " to the ISO Central Secretariat for circulation as a FDIS ballot via the Vienna Agreement with ISO lead. A revised document, separate revisable figure files and a completed table of comments will arrive at the TC secretariat no later than 1 February 2011.		AU: IT-014 to consider engagement strategy involving IT-014-02 IT-014-06-04 TGA

Resolution	Further action	By
40. Resolved that ISO/TC215 approves the WG 6 recommendation that the ISO/TC215 Secretariat forward prEN ISO 27953-2 <i>"Health informatics – Pharmacovigilance – Individual case safety report – Part 2: Human pharmaceutical reporting requirements for ICSR"</i> to the ISO Central Secretariat for circulation as a FDIS ballot via the Vienna Agreement with ISO lead. A revised document, separate revisable figure files and a completed table of comments will arrive at the TC secretariat no later than 1 February 2011.		AU: IT-014 to consider engagement strategy involving IT-014-02 IT-014-06-04 TGA
41. Resolved that ISO/TC215 approves the WG 6 recommendation that the ISO/TC215 Secretariat circulates the DTR ballot of ISO 14872 <i>"Health informatics – Requirements for the implementation of the standards for the identification of medicinal products for the exchange of regulated medicinal product information"</i> for approval as a Technical Report and that the document arrives at the TC Secretariat no later than 1 December 2010 to be placed on the ISO/TC web site no later than 15 December 2010.		AU: IT-014 to consider engagement strategy involving IT-014-02 IT-014-06-04 NEHTA (AMT)
42. Resolved that ISO/TC 215 accepts the report of ISO/TC 215 WG 7.	Summary presentation by WG convenor available with minutes	WG Convenor TC 215 Secretariat
43. Resolved that ISO/TC215 approves the WG7 recommendation to present Preliminary New Work Items for International Standards on the following IEEE 11073 projects, 11073-10419 Health informatics - Personal health device communication - Device specialization - Insulin pump 11073-10420 Health informatics - Personal health device communication - Device specialization - Body composition analyser 11073-10421 Health informatics - Personal health device communication - Device specialization - Peak expiratory flow monitor (peak flow) 11073-10418 Health informatics - Personal health device communication - Device specialization - INR analyser 11073-10413 Health informatics - Personal health device communication - Device specialization - Respiration rate 11073-10443 Health informatics - Personal health device communication - Device specialization - Physical activity monitor		AU: IT-014 to decide approach for responding to these medical device ballots
44. Resolved that ISO/TC 215 accepts the report of ISO/TC 215 WG 8.	Summary presentation by WG convenor available with minutes	WG Convenor TC 215 Secretariat
45. Resolved that ISO/TC215 approves the WG 8 recommendation that the work item ISO 14639-1 <i>"HI - Business requirements for an e-health architecture for developing and emerging countries - Part 1: Environmental Scan"</i> be renamed ISO 14639-1 <i>"HI - ehealth architecture roadmap Part 1: Overview of national ehealth initiatives"</i> .	Renaming of work item	TC 215 Secretariat

Resolution	Further action	By
46. Resolved that ISO/TC215 approves the WG 8 recommendation that the work item ISO 14639-2 " <i>HI - Business requirements for an e-health architecture for developing and emerging countries - Part 2: Business requirements</i> " be renamed ISO 14639-2 " <i>HI – Capacity-based ehealth architecture roadmap Part 2: Architectural components and maturity model</i> ".	Renaming of work item	TC 215 Secretariat
47. Resolved that ISO/TC215 approves the WG 8 recommendation for a six week informal review period by the ISO-215 experts then ISO/TC215 Secretariat is requested to circulate the DTR ballot of ISO 14639-1 " <i>HI – Capacity-based ehealth architecture roadmap – Part 1: Overview of national ehealth initiatives</i> " for approval as a Technical Report and that the document arrives at the TC Secretariat no later than January 14, 2011 to be placed on the ISO/TC web site no later than February 4, 2011.		AU: IT-014 to note AU: IT-014-09 for ballot response RDH, AM participate as experts
48. Resolved that ISO/TC215 approves the WG 8 recommendation the for a six week informal review period by the ISO-215 experts then ISO/TC215 Secretariat circulates the DTR ballot of ISO 13054 " <i>HI – Knowledge management of health information standards</i> " for approval as a Technical Report and that the document arrives at the TC Secretariat no later than January 14, 2011 to be placed on the ISO/TC web site no later than February 4, 2011.		AU: IT-014 to note AU: IT-014-02 for ballot response
49. Resolved that ISO/TC215 approves the WG 8 recommendation that the ISO/TC215 Secretariat circulates the DTR ballot of ISO 14292 " <i>HI – Personal health records - definition, scope and context</i> " for approval as a Technical Report and that the document arrives at the ISO/TC Secretariat no later than October 14, 2011 to be placed on the ISO/TC web site no later than November 5, 2011.		AU: IT-014 to note AU: IT-014-09 for ballot response
50. Resolved that ISO TC215 WG8 thanks GEN TC 251 WG1 for sharing its working documents, Technical Reports on Use Cases and Enterprise Architecture on an ongoing basis and looks forward to a continued sharing relationship.	For noting in minutes	TC 215 Secretariat
51. Resolved that ISO/TC215 accepts the reports from: TC215 Reorganization Task Force, JTC1 Liaison and the Patient Safety and Quality Task Force.	Summary presentations by WG available with minutes	JTC1 Liaison Officer PSQ TF Convener TC 215 Secretariat
52. Resolved that ISO/TC215 thanks Ms. Atsuko Saruhashi, our Technical program Manager from ISO Central Secretariat for her kind technical assistance.	For noting in minutes	TC 215 Secretariat
53. Resolved that ISO/TC215 thank our host, NEN, especially Shirin Golyardi, Mary van den Berg-Boeters, Karin van der Lubbe and the Erasmus University for their excellent meeting arrangements and social event, as well as their assistance throughout the meeting, which contributed to a successful and productive meeting.	For noting in minutes	TC 215 Secretariat

Resolution	Further action	By
54. Resolved that ISO/TC215 acknowledges and thanks the Observing country Singapore for the contribution of their members to the ISO/TC215 Plenary meetings.	For noting in minutes	TC 215 Secretariat
55. Resolved that ISO/TC215 approves that the next ISO/TC215 Plenary Meeting will be held in Kupio, Finland, 23–27 May 2011.	Notice of meeting to be given NMBs & delegations to note dates + plan attendance	TC 215 Secretariat NMBs (Standards Australia & IT-014)

26.2 RESOLUTIONS NOT APPROVED

On this occasion all proposed resolutions were passed.