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International Delegates Meeting Report

Refer to the last page for guidelines on completing this report

Date:	21 August 2017
Delegate(s) proposed by:	
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International Committee details:	ISO	TC 215 Health informatics, including opening/ closing plenary and meetings of: TC 215/CAG1, CAG2, WGs and Joint Initiative Council (JIC) for global health informatics standardization
Meeting/Committee type:	Technical Meeting	
Australian Participation:	P-Member	

Meeting date & venue:	
Date	**Mon 2017-04-17 to Friday 2017-04-21**. TC 215 including leadership meetings, opening plenary, 3 days WG meetings, and closing plenary. Also: **Sunday 16-04-2017**. Joint Initiative Council (JIC) for Health Informatics Standardization – Face-to-face meeting of JIC Executive Some of the ISO/TC215 leadership team (including Heather Grain as WG3 convenor) also presented at the International Health Informatics Standardization Forum hosted by the Hangzhou Municipal Government and the China National Institute of Standardization in the afternoon of 2017-04-17.

Venue details	All meetings (including JIC and the International Health Informatics Standardization Forum were held at: Zhejiang Hotel, 278 Santaishan Road Hangzhou, Zhejiang Province, China.

Australian delegates:	J Richard DIXON HUGHES (RDH), Head of delegation & expert – mainly at leadership meetings and WG1; also immediate past-chair of the JIC Heather GRAIN (HG) - Convenor, ISO/TC 215/WG 3 Semantic content A/Prof Trish WILLIAMS (TW), expert – mainly at WG 4 and JWG 7 Note: Dr Vincent McCauley also attended. Whilst he is an Australian expert on several TC 215 projects, for this TC 215 meeting he was nominated as an IHE liaison and was not a member of the Australian delegation.

Purpose of meeting:	The purpose of the meeting was to progress the TC 215 work program comprising around 50 active projects and to review potential new projects in the field of health informatics, including joint work with other ISO and IEC technical committees. Australian involvement is significant in terms of monitoring and participating in health informatics standards work on behalf of the Standards Australia IT-014 mirror committee, particularly through: • TC 215 leadership roles (where RDH and HG both serve on CAG1 Executive Council and the CAG2 Coordination Group, and RDH is Immediate-Past Chair of the JIC, and ISO/IEC JTC1 liaison to TC215.. • WG3 (Semantic content – where Heather Grain is the convenor and leader of several projects), • WG4 and JWG7, where Trish Williams is a leader of projects on health software safety and information security

Meeting attendees:	The following 16 P-members were represented at the TC 215 meeting, which had a total attendance of over 150 people. • Australia • Canada • China • Czech Republic • Germany • Ireland • Italy • Japan • Korea • The Netherlands • Russian Federation • Spain • Sweden • Switzerland • United Kingdom • United States Liaison organisations represented included GS1, IHE international, JTC1, CDISC, COCIR, IMIA, IEEE and several ISO and IEC committees. The total attendance also included observers, and the ISO/TC215 secretariat.

	The JIC Executive met at the same venue immediately prior to the ISO/TC 215 meeting with CEN/TC 251, HL7 International, CDISC, IHTSDO, GS1, and IHE International present. SNOMED International and DICOM were apologies.

Key items discussed:	**ISO/TC 215 – General (Plenary sessions, CAG 01 and CAG 02):** • TC 215 strategic business plan (SBP). Since the previous meeting, v4.11 of the SBP (dated 2016-11-16) has been published on the ISO website. • Outcomes of consultation and ISO/TMB approval of changes to the ISO/TC 215 scope statement arising from the SBP development process. • Activities of ISO/TC 215/TF 1 (Task Force 1) on quantities and units in healthcare - and progress toward resolution of related issues in collaboration with the ISO/TC 12 and IEC/TC 25 (Quantities and units) committees. • TC 215 liaisons – progress with rationalisation and renewal based on report of the TC 215 Secretariat to the previous TC 215 meeting. • Report of the Ad Hoc Group on Aging Communities. • Continued consultation (with TC249 and TC 215/TMsTF) surrounding the proposed formation of an ISO/TC 215 Working Group in the area of Health Informatics - Traditional Medicines. • JTC 1 Liaison report (presented by RDH) and potential to progress increased collaboration following the November 2016 joint leadership meeting of ISO/TC 215 and ISO/IEC JTC 1 in Lillehammer. • CAG 02 – frequency of CAG 02 meetings and changes in process to realise the role of CAG 02 in review and coordination of new work item proposals. • CAG 02 – frameworks for working groups to use in planning future work and assessing proposals for new standards development work. • CAG 02 – progressing the use and governance of SKMT (Standards Knowledge Management Tool) within TC 215 and the wider health informatics SDO community. • Update on JIC activities – notably work on the Patient Summary Standards Set (PSSS) – aiming for publication in or around September 2017. • ISO/TC 215 meeting calendar - locations and dates for future TC 215 meetings. • Impact of changes in the 2017 Edition of the ISO/IEC directives on practices and processes followed by TC 215 and its WGs. • The Olympics Healthcare Interoperability (OHI) initiative, which is being now led by HIMSS with support of JIC. • Noting liaison reports from ISO/TC 12, ISO/TC 42, ISO/TC 46, ISO/TC 210, ISO/TC 212, ISO/TC 249, ISO/TC 292, ISO/TC 304, JTC 1/SC 6, COCIR,DICOM, HON, IEEE, and IHE International.

- Presentations to the closing plenary on the activities of each of the Work Groups and proposed resolutions for TC 215 approval (as covered elsewhere in this report).

WG 1 Architecture, frameworks and models (joint with CEN/TC 251/WG i):

Activities in WG 1 were covered by Richard Dixon Hughes in parallel with his attendance in WG 2 and TC 215 leadership roles. Items addressed by WG 1 included:

- Developing a framework to guide the work of WG 1 – building on the concepts that had been initiated by WG 3 in their framework and the subsequent discussion of frameworks in CAG 02 and CAG 01.
- Discussion and provision of feedback on suggestions that TC 215 consider moving from WGs to a subcommittee structure.
- Status and progression of *ISO/PRF TR 19669 Health informatics -- Re-usable component strategy for use case development.*
- Status and progression of Edition 2 of *ISO 13606 ..* [1] *EHR Communication (EHRcom) - Parts 1 to 5.* (jointly with CEN/TC 251 and with WG 4 for Part 4)
- Joint discussion with WG3, in relation to:
  - Suggestions for evolution of the WG3 framework for WG planning
  - Progress with adoption and application of SKMT, including governance issues around standards and terminology harmonisation
  - Status and progression of ISO/NP TS 22287 Workforce roles and capabilities for terminology and terminology services (Term Workforce), and the potential for similar work (in collaboration with WG 3) on information modelling and architectures.
- Status and progression of ISO/PWI and work on *Quality management requirements for patient registries*.
- Status and progression of JIC work on the *Patient Summary Standards Set (PSSS) - i*n joint session with WG2.
- Status and progression of *ISO/NP 22272 DTR .. Methodology for enterprise business and information management needs analysis to support standards-based architectures*.
- Status and progression of Edition 2 of *ISO 12967 Health informatics – Services architecture (HISA) - Parts 1, 2 and 3*.
- Status and finalisation of *ISO/DTS 18864, Health informatics, Quality metrics for detailed clinical models*.
- Presentation of work on HL7 *EHR-Functional Model profile for Immunisations* and invitation for TC 215 experts to participate.

[1] In this report, the words “Health informatics - ” which appear almost all TC 215 publication titles are often abbreviated to “.. ” (i.e. two dots). Three or more dots indicates a different or longer break in the text.

- Status and progress of work being done by the TC 215 *Ad Hoc Group on Health Informatics for Aging Communities* (in joint session with WG2)
- Need for RDH to progress and report back on systematic review of *ISO/TS 21667:2004 Health informatics - Health indicators conceptual framework*.
- Status and progression of *ISO/DTS 21089 ..Trusted end-to-end information flows*.

WG 2 Systems and device interoperability

Some activities in WG 2 were covered by Richard Dixon Hughes in parallel with his attendance in WG 1 and TC 215 leadership roles. Items addressed by WG 2 included:

- Status and progression of *ISO DTR 21835 Clinically relevant data which a person generates daily* (project re-named as: *"Health-related data which a person generates daily"*)
- Status and progression of *ISO/DTR 20055 .. Person-owned document repository for PHR applications and health information exchange*.
- Status and progression of *ISO/NP TR 20841 .. Trans-national health record*.
- Status and progression of *ISO/PWI TR 22228 .. Healthcare applications of blockchain technologies*.
- Proposal for ISO/PWI on: *Structured clinical gene fusion report in electronic health records*.
- Presentation by Mike Nusbaum (IHE/HIMSS/JIC) on the status and progress of the Olympics Health Interoperability (OHI) initiative.
- In joint session with WG3 - direction and scope of: *ISO/PWI 17583 .. Terminology constraints for coded data elements expressed in ISO harmonized data types used in healthcare information interchange (Binding)*.
- Status and progression of *ISO/NP 21860 .. Reference standards portfolio for clinical imaging (RSP-CI)*, in joint session with WG 3.
- Status of joint work by CDISC and HL7 on *BRIDG v5* and proposal to progress it to DIS via an ISO/NP (in joint session with WG3).
- Joint discussion with WG3, in relation to: development, adoption, application and governance of SKMT.
- Status and progression of *ISO/PWI 22218 Common Specification for output data of Ophthalmic Examination Equipment* (project re-named as: *"Ophthalmic examination device data"*).
- Status and progression of *ISO/NP TR 21393 .. Omics Markup Language (OML)*.
- Status and progression of *ISO/NP TR 25720 .. Whole Genomic Sequence Markup Language (WGSML)*.

- Status and progression of *ISO/PWI 22227 Proposal to Standardize Laparoscope/Endoscope Intervention* (project re-named as: "*Endoscopy and related data*").
- Presentation and proposal for an ISO/PWI on: *Reliability assessment criteria for high-throughput gene-expression data.*
- Status and progression of *ISO/NP TS 22077-4 Medical waveform format Part 4: Stress test electrocardiography*.
- Status and progression of *ISO/PWI 22077-5 Medical waveform format - Part 5: EEG*.
- Presentation and proposal for an ISO/PWI on: *Reliability assessment criteria for token-based document sharing*.
- Proposal for an ISO/PWI on: *Reliability assessment criteria for quality control metrics for DNA sequencing*.
- In joint session with WG1 - status and progression of JIC work on the *Patient Summary Standards Set (PSSS)* – and the potential for elements of this to become the basis for future RSPs within TC 215.
- Updates on other international work on shared patient summaries (in joint session with WG1).
- Status and progress of work being done by the TC 215 *Ad Hoc Group on Health Informatics for Aging Communities* (in joint session with WG1)
- Status and progression of *ISO/IEEE 11073 personal health device communications standards* program.
- Agreed need for a strategic plan be developed to address all the genomics-related topics coming into TC 215, particularly through WG2 (proposed by Richard Dixon Hughes).

WG 3 Semantic content.

Matters discussed in WG 3 included the following, with more detailed observations being provided by Heather Grain in her report (at Appendix A).

- Status and progression of *ISO/DTS 21564 Health informatics, Terminology Resource Map Quality Measures (MapQual)*.
- Status and progression of *ISO/DTS 21526 .. Metadata repository requirements in healthcare (MetaReq).*
- Status and progression of *ISO/NP TS 22287 Workforce roles and capabilities for terminology and terminology services (Term Workforce)* – in joint session with WG1.
- WG 2 report on progress of *ISO/NP 21860 .. Reference standards portfolio for clinical imaging (RSP-CI).*
- Potential work with WG 2 and/or HL7 on *ISO/PWI 17583 Terminology constraints for coded data elements* – including issues flowing from

	systematic review of *ISO 21090:2011 Health informatics, Harmonized data types for information interchange* and binding to FHIR data types. • WG 2 report on progress of *BRIDG v5* and further work on related CDISC standards, including incorporation of DICOM imaging material. • WG 6 report on status and progression of *ISO/DTR 14872 .. IDMP – Core principles of maintenance of identifiers and terms*. • Potential WG 6 work on requirements governing the nature and use of clinical decision support applications in conjunction with clinical knowledge bases in the pharmacy domain. • Potential WG 6 work on requirements governing the nature and use of clinical decision support applications in conjunction with clinical knowledge bases in the pharmacy domain. • Potential WG 6 work on medication safety alerts. • Status and progression of *ISO/CD 17117-1 .. Terminological Resources, Part 1: Characteristics (TermChar)* to DIS ballot. • Status and progression of work on updating *ISO 17115:2007 .. Vocabulary of compositional terminological systems* (project re-named as: "*representation of categories, constraints and associations between categories needed to express terminology (CatStructure)*") • Status of ISO/PWI on Healthcare Terminology Implementation Capability and Maturity Models Capability (TICMM-1) – to become parts 2, 3 and 4 of *ISO 17115*. • Status and progression of draft to DIS ballot for Edition 2 of *ISO 13120 .. Syntax to Represent the Content of Healthcare Classification Systems - Classification Markup Language (ClaML)*. • Potential ISO/PWI DTS on: *Health informatics – Value set design and governance* • Potential for WG 3 to create RSP "bundles" based on referencing existing and proposed terminology standards in different contexts – e.g. implementation and use of terminology, development of terminologies and classifications, and governance of terminology. **WG 4 Security, Safety and Privacy** Matters discussed in WG 4 included the following, with more detailed observations being provided by Prof Trish Williams in her report (at Appendix B). • Joint work with JWG 7 on *Risk management, security and privacy* for 81001– including responsibility and standards for security of medical devices. • Status and progression of *ISO/NP TS 11633 .. Information security management for remote maintenance of medical devices and medical information systems - Part 1: Requirements and risk analysis* (update to previous ISO/TR of the same name).

- Proposal for a PWI for an ISO/TR on: *Guideline for authentication framework of the networked smart healthcare devices*.
- Systematic review of *ISO/TS 14441:2013 Security and privacy requirements of EHR systems for use in conformity assessment*.
- Proposed systematic review of *ISO/NP 17090-4 .. Public key infrastructure – Part 4: Digital Signatures for healthcare documents (Ed 2)*.
- Proposal for a PWI for an ISO/TR on: *Guidance for an identification and authentication framework of networked personal health devices*.
- Status and progression of *ISO/PWI 20429 Health informatics - Principles and guidelines for protection of personal health information.*
- Status and progression of *ISO/PWI TR 21332 Cloud computing considerations for health information systems security and privacy*.
- Status and progression of *ISO/PWI TS 20405 ..Framework of event data and reporting definitions for the safety of health software*.
- Potential harmonization of: IHE *Audit Trail Node Authentication (ATNA) Integration Profile* with ISO *27789 .. Audit Trails for electronic health records.*

WG 6 Pharmacy and medicines business

The Australian delegation did not have sufficient resources to cover WG 6 work in any depth. Topics reported to have been addressed included:

- IDMP (Identification of Medicinal Products) standards and their application – including a half-day workshop.

  Current work on IDMP is nearing completion, with a major focus on adoption and implementation by the pharmaceutical companies and regulators in Europe, the US and some other countries. Future editions will build on experience in implementing current versions.
- Potential new work Items and strategic planning topics for WG 6.
- Proposal for an ISO/NP for a TS on: *Requirements for a knowledge base for clinical decision support system* [ISO/NP 22756].
- Proposal for an ISO/NP on: *Requirements for Medication Safety Alerts* [ISO/NP 22703].
- Status and progression of *ISO/DTR 20831 .. Medication management concepts and definition*.
- Status and progression of *ISO/DTR 14872 ..Core principles for maintenance of identifiers and terms* (in joint session with WG3).
- Status and progression of *ISO/DTS 19293 Requirements for the record of dispense medicinal products*.
- Pre-ballot review and progression of *ISO 11238 .. IDMP- Data Elements and Structures for the Unique Identification and Exchange of Regulated Information on Substances* (Ed 2).

	• Pre-ballot review and progression of *ISO/DTS 19844:2017 .. IDMP – Implementation guide for ISO 11238 for Data elements and structures for the unique identification and exchange of regulated information on substances* (Ed 3). • Process for progression to publication of: - *ISO 11615 Health informatics .. IDMP - Data elements and structures for the unique identification and exchange of regulated medicinal product information*; - the associated: *ISO/DTS 20443 .. IDMP - Implementation guide for ISO 11615 Data elements and structures for the unique identification and exchange of regulated medicinal product information*; - *ISO 11616 .. IDMP- Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*; and - the associated: *ISO/DTS 20451 ,, IDMP - Implementation guide for ISO 11616 Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*. • Possible future work to develop a TS on: Mobile access to patient information with automatic identification and data capture (AIDC) – using 2D barcodes on medication packaging to enable online retrieval of information about the medication, including warnings and instructions for patients. • Possible changes to the Individual Case Safety Reports (ICSR) standards (or the development of similar parallel standards) to provide case safety reporting for devices (in addition to pharmaceutical products). • The potential to develop a standardized Regulated Product Submission (RPS) for medical devices (currently under consideration at IMDRF). • SKMT. Each WG is being asked to volunteer one project to have its terms and definitions entered into the SKMT in a controlled process, and to provide feedback on SKMT efficiency and requests for improvement. • Presentation on the Olympics Healthcare Interoperability Initiative. • Proposals for future joint meetings with the HL7 Pharmacy WG and IHE Pharmacy SIG. **JWG 1 Joint ISO/TC 215 - ISO/TC 249 WG: Traditional Chinese Medicine (Informatics), and Traditional Medicines Taskforce (TMsTF)** The Australian delegation did not have sufficient resources to cover JWG1 and TMsTF work in any depth. Topics reported to have been covered included: • Status and progression of *ISO/DTS 16843-3 .. Categorial structures for representation of acupuncture -Part 3: Moxibustion*. • Status and progression of *ISO/DTS 16843-4 Health informatics Categorial structures for representation of acupuncture -Part 4: Meridian and collateral Channels*.

	• Progression to 12-week NP Ballot of *ISO/PWI TS 22773 .. Categorial structures for representation of decocting process in traditional Chinese medicine*. • Progression to 12-week NP Ballot of *ISO/PWI 21831 .. Categorial structures for representation of processing Chinese materia medica*. • Progression to 12-week NP ballot of *ISO/PWI 22835 .. Categorical structures for combinations of traditional medicines*. • Progressing the proposed establishment of a separate Traditional Medicines working group (TMs WG) within TC 21 - to replace the TMsTF. There were joint discussions around the operating procedures and mechanism for co-ordination with JWG 1 and TC 249 (Traditional Chinese Medicine). These need to be agreed and documented prior to the establishment of the new WG – and are expected to include all work proposals for the new TMs WG being assessed by JWG1 (with a turn-around of no more than one month). • Preliminary work items proposed by Korea to the TMsTF (to be considered at the next TC 215 meeting and done in collaboration with TC 249, TC 215/ WG 3 and potentially the US-FDA): - Traditional medicinal herbal product standard using IDMP - Requirements for ontological concept of traditional medicinal products. • The next meeting of JTC 1 – taking place in conjunction with the TC 249 meeting in Hong Kong on 5-8 June 2017.
	JWG 7 Joint ISO/TC 215 - IEC/SC 62A WG: Safe, effective and secure health software and health IT systems, including those incorporating medical devices Information on matters discussed are covered in the report from Prof Trish Williams, which is substantially reproduced in Appendix B below, and include: • Status and progression of work on *ISO/AWI 81001-1 Health software and health IT systems safety, effectiveness and security - Part 1: Foundational principles, concepts, and terms*. This work also supports the current revision of the various parts of IEC+ISO 80001 and included discussion of work done by a tiger team. • Status and progression of the revision of *ISO 14971:2007 Medical devices -- Application of risk management to medical devices*, to include refining and broadening the definition of “harm” from purely physical harm to patients and recognising cybersecurity risks to the safety of devices. • Potential for new work on Mobile App Development based on PAS 277 (CEN251)

	JIC - Joint Initiative Council for Global Health Informatics Standardization On the day before the TC 215 closing plenary, a half-day, face-to-face meeting of the JIC Executive was held at the TC 215 venue. As immediate past chair of JIC and one of the TC215 nominees, RDH was among the JIC executives present. Matters discussed included: • Development of the JIC role and better communication of its activities including updating the website – resulting in the formation of a task force chaired by Mike Glickman (ISO/TC 215) to carry out a review and make recommendations. • Process for on-boarding new JIC members, in preparation for considering the application from the Personal Connected Health Alliance (PCHAlliance) – with RDH presenting on relevant aspects of the JIC charter and rules. • Status and plans for finalisation of the JIC Patient Summary Standard Set (PSSS) project – with the aim of sign-off for publication in November [see further report under observations on WG 1 below]. • Plans for JIC review of the EU eStandards Development Roadmap. • Potential for a major activity, such as a follow-up to the eHealth Summit program. • Progressing collaboration on a joint statement about HL7/FHIR. A number of key members of the JIC Executive (including Don Sweete, the Chair, and the Secretariat) were unable to attend the Hangzhou face-to-face meeting primarily due to the proximity to the SNOMED International Business Meeting in London the following week and several major eHealth activities in Europe in the subsequent weeks; however, the meeting was still productive and enabled the incoming Chair, Mike Nusbaum, to become more actively involved in setting the agenda for his tenure.

Confirm net benefit to Australia in participating:	The meeting was significant because some of the items under discussion address identified Australian requirements, may be relevant for local adoption, are of interest to ADHA or Australian jurisdictions as represented by the AHMAC/NHCIOF, are being worked on by Australian experts and/or are being implemented in Australian health care services. Benefits of Australian participation include: • Ability to understand and influence the direction of current and proposed TC 215 work items with over 15 projects coming to ballot and a further 8 reviews by WG experts planned prior to the next TC 215 meeting in April 2017, and many other projects at the PWI stage. • Ability to pursue opportunities to promote the recognition and/or adoption of existing Australian work at international level, particularly in relation to

	aspects of identification, privacy and security, health software safety and e-health interoperability frameworks. • Ability to progress the interests of Australian jurisdictions (as reported from the AHMAC Health CIO Forum) in standards for the governance, management and use of clinical terminologies and coding systems, with Australia being accepted to lead the TC 215 work items most relevant to Australian needs in these areas. • Developing international standards to support Australian initiatives to map commonly used interface terminologies to the Australian implementation of SNOMED CT® thereby enabling improved use of health information for shared clinical care, administrative and statistical reporting. • Monitoring and participating in TC 215 work on security, safety, privacy and trans-border data flows that is potentially relevant to Australian practices and initiatives for sharing and use of health record information. • Ability to monitor, participate in and influence the revision and restructure of the ISO/IEC 80001-series, IEC 82304-1 and related developments in health software risk management standards. These are likely to have global impacts on the regulation of health software and devices. The IEC 80001 standard has been applied in some jurisdictions (including QLD and NSW). • The proposed revision to the 80001-series and the creation of the new ISO 81001-series of foundational documents will impact medical devices (both traditional and software-based devices) from their manufacture through deployment and implementation, to retirement • In Australia, the local health software industry has expressed interest in IEC 82304-1, the impacts of the revision of the ISO+IEC 80001-series in JWG 7 and their potential relevance to Australia and its global markets • Promoting Australian expertise and leadership of standards related to Digital Health/eHealth software safety, security and privacy, ensuring that international developments are compatible with Australian best practice and are informed by Australian regulatory requirements. • Opportunity to receive input and provide feedback on the operation of ISO/CS policies and systems as they affect Australian experts working on health informatics standards (which often involves the complexity of working across and reconciling the approaches of multiple SDOs – ISO, HL7, CEN, IHTSDO, GS1, IHE, DICOM, IEEE, PCH Alliance and Continua Alliance, ITU-T, CDISC, OASIS, W3C/IETF, JTC1 and others). • Ability to promote Australia, its standards community and our commitment to best practice in international standardization and to influence the leadership of TC 215 to embrace harmonisation of the various Digital Health/e-health standards used in Australia and internationally and, where possible, support the use of TC 215 as a peak agent for the release of internationally agreed and harmonised specifications. • Supporting the need for international standards that focus on policy, governance and functional best practice applicable to implementation of the Digital Health/eHealth agenda

	• Improving Australian capacity to implement health informatics standards and eHealth systems by expanding local knowledge and expertise based on international best practice. • Continuing to lead and promote the development and use of consistent terminology and an approved lexicon of terms and thesaurus for use across ISO and other health informatics standards. • Supporting the liaison between ISO/TC 215 and ISO/IEC Joint Technical Committee 1 (JTC 1) with a view to encouraging collaboration on IT standards affecting health care delivery and avoiding duplication of work.

Observations & comments:	**General.** Australian involvement is significant in terms of monitoring and participating in relevant TC 215 health informatics standards development work on behalf of IT-014 mirror committee, particularly through: • WG1 (Architecture, framework & models) – where RDH is active as a nominated expert; • WG3 (Semantic content) – where Heather Grain is the convenor of the WG and leader of several projects. • WG4 (Security, Safety & Privacy) – where Trish Williams is active as leader of several projects and several other Australians (including RDH and VMcC) are nominated experts. • JWG 07 (Joint WG with IEC/SC 62A: Safe, effective and secure health software and health IT systems, including those incorporating medical devices) – where several Australians (including TW, RDH, Dr Vince McCauley (VMcC), Kathy Dallest and Edmund Keinast) are active members on projects to produce updated health software risk management standards which will impact the regulation of health software and devices. • TC215 leadership roles - where RDH and HG both serve on TC 215/CAG01 Executive Council, CAG02 Coordination Group and participate in the Operations Advisory Group (OAG). RDH is a member and former co-chair of the TC 215 Strategic planning task force and is the current ISO/IEC JTC1 liaison to ISO/TC 215. • RDH served as Chair of the JIC for 2013 and 2014 (with Australian Government support) and continued his participation in the JIC Executive as immediate past chair and as one of the ISO/TC 215 representatives. **ISO/TC 215 plenaries, CAG 01 and CAG 02** Observations reported on and matters addressed included: • **ISO/TC 215 Strategic Business Plan Version 4.11**, as approved on 16 November 2016, has been loaded onto the ISO website following review and acceptance by ISO. • **Changes to the ISO/TC 215 scope statement** that arose from the SBP process were reported to have been approved by ISO/TMB, despite some ongoing objections from elements within IEC/TC62. At the date of compiling this report, the revised scope statement had still to be reflected on the ISO website. This has been brought to the attention of the TC 215 Secretariat and Chair. • **TC 215 structure**. Flowing on from work on the SBP, suggestions have been received that TC 215 should re-visit the question of moving to a structure where the work is principally progressed via constituted subcommittees, rather than through standing working groups. It was noted that this structure would align more closely with the governance arrangements foreshadowed in the ISO Directives and may make it easier to attract secretariats and convenors. On the other hand, the current TC 215

	structure had been adopted to facilitate coordination across the streams and the need for many experts to attend and participate in various aspects of the work. The tendency is for subcommittees to meet separately and this would need to be managed. Much of the pressure to change had come from IEC representatives on JWG7; however, one of the problems with moving to SCs is that there is no provision for joint SCs. There was much discussion as to the pros and cons of the various approaches – with CAG02 being asked to review the question and report back at the November 2017 meeting in Liverpool, UK. • **ISO/TC 215/TF 1 (Task Force 1) on quantities and units in healthcare** is working with ISO/TC 12 and IEC/TC 25 (Quantities and units) to resolve issues around standards used for quantities and units used in health/e-health and their relationship to quantities and units defined by ISO/TC 12 and IEC/TC 25. An online survey had been set up (extended to close in mid-May) to identify the systems of units and standards currently in use, and potential gaps and overlaps. As at the date of the meeting, 84 responses had been received, with delegates being encouraged to get others to respond before the survey closed. RDH continues to be involved as one of the principal authors of the survey and will assist the drafting group in reporting on its outcomes. • **TC 215 liaisons**. Following on from the review of TC 215 liaisons by the TC 215 secretariat and subsequent CI ballot (as discussed at the November 2016 meeting), 11 internal liaisons that were proposed to be discontinued on the grounds that they had no work in common were contacted and one responded; the TC 215 Secretariat proposed discontinuing the other 10. It has been clarified that that requests for internal liaison from other ISO committees are automatically granted, allowing them to receive access to TC 215 information; however, that does not require TC 215 to have a reciprocal liaison relationship. The following 9 internal liaisons from TC 215 were discontinued by resolution at this meeting: 1 ISO/TC 42 Photography 2 ISO/TC150 Implants for surgery 3 ISO/TC 168 Prosthetics and orthotics 4 ISO/TC 172 Optics and photonics 5 ISO/TC 194 Biological and clinical evaluation of medical devices 6 ISO/TC 198 Sterilization of healthcare products 7 ISO/TC 229 Nanotechnologies 8 ISO/IEC JTC 1 /SC2 Coded character sets 9 ISO/IEC JTC 1/SC 24 Programming languages, image processing and environmental data representation Following discussion, the TC 215 plenary resolved to retain the liaison relationship to *ISO/IEC JTC 1/SC 7 Software and systems engineering*, and appoint Celestina Bianco (Spain) as liaison officer pending NMB approval.

The Secretariat is continuing to review its review of the 16 external liaisons.

The call for liaison officers to service many of the other liaisons remains open and suitable candidates are welcome.

- **Ad Hoc Group on Aging** [Ageing] **Communities – progress report.** At the November 2016 TC 215 meeting, an Ad Hoc Group (AHG) was formed under the leadership of Todd Cooper (US), Dr.Il Kon Kim (KR), Dr. Sungkee Lee (KR) to focus on Health Informatics for Aging Communities.

  The AHG on Aging Communities reported several times during the meeting, including to CAG 01 and, in detail, to a joint session of WG 2 and WG 1. [Reported further under WG 2].

  It was noted that in March 2017, ISO had announced the formation of a Strategic Advisory Group (SAG) on Ageing Societies to help inform its future work in supporting the demographic shift toward older populations in many parts of the world. The SAG will be led by BSI (UK) and comprise experts from various areas including government, community infrastructure, research and the aged care industry, and will investigate how standards can help solve the challenges posed by ageing populations.

  The TC 215 AHG on Aging Communities is aiming to be well positioned to make informed input by the time of the next TC 215 meeting in November.

- **ISO/TC215 welcome to Prof Haiyan Li**, the co-convenor of TC 215/JWG 1 (*Joint ISO/TC 215-ISO/TC 249 WG: Traditional Chinese Medicine Informatics*), following his appointment to the position by ISO/TC 249 (Traditional Chinese Medicine).

- **Issues surrounding the proposed formation of an ISO/TC 215 Working Group in the area of Health Informatics - Traditional Medicines**.

  The formation of a TMs WG (and associated retirement of the TMsTF) has been approved in principle by TC215 but deferred until there are specific TC 215 work items approved for it to progress independently of JWG 1 or by TC 249 (Traditional Chinese Medicine). The TMsTF is assessing two proposals for new work proposed by Korea, as potential candidates for the first items to be developed by the new WG.

  Some of those in TC 249 have held the view that there is not much scope for TC 215 work in the area of traditional medicines informatics that could not be better addressed through JWG 1 rather than the proposed TMs WG

  The differentiator is that JWG1 and TC 249 work on content related to traditional Chinese medicine, whereas the TMsTF (and subsequent TC 215 WG) will focus on information structure and content related to other types of traditional medicine.

  Nevertheless, because of a high degree of overlap, standardisation activities need to be coordinated and compatible across all traditional medicine domains and with the structures being used in other areas of health informatics supported by TC 215.

  The Hangzhou meeting provided a good opportunity for the various parties to work through the issues on how they can best collaborate – with an understanding that JWG 1 will have a month to consider and comment on

how any work item proposed by the TC 215 TMsTF and/or WG should be managed and coordinated with other work in TC 249 and JWG 1.

The current Chair of ISO/TC 249 until December 2018 is Dr David Graham, an Australian.

- **JTC 1 Liaison report**. This was presented by RDH and encouraged consideration of areas for potential increased collaboration (following the November 2016 joint leadership meeting of ISO/TC 215 and ISO/IEC JTC 1 in Lillehammer).
- **Impact of changes in the ISO/IEC Directives**. Changes in the May 2017 edition noted as potentially impacting TC 215 work included:
  1 A new 18-month track may be nominated for work items at NP ballot.
  2 An NP ballot requires affirmative votes from at least 2/3 of P-members voting in order to be approved.
  3 Revised rules require the progression of an approved DIS directly to publication without an FDIS but not where there are technical edits and/or FDIS is otherwise required under the Vienna Agreement (VA) - for joint work with CEN.
  4 All technical feedback on a document (including comments from those who voted negatively on approved DIS/FDIS ballots) should be retained in a committee/project folder for use in later reviews.
  5 A TC is required to review its Strategic Business Plan (SBP) at least every 3 years, taking into account comments received.
  6 P-members of TCs are now also obligated to vote on all CIBs and SRs to avoid losing their status as voting P-members.
  7 Increased use of Webex and electronic meeting allowed (including some TC meetings – see TMB communiqué Sep 2016).
  8 Documents submitted for FDIS and/or publication need to be based on the version distributed for DIS/DTS ballot as this version may contain ISO edits that would otherwise be lost.

  TC 215 internal templates and processes have been modified to reduce superfluous balloting that had traditionally been done to confirm the passage of documents from an affirmative CD ballot to the DIS, DTS or DTR ballot stage, and from affirmative DIS or FDIS ballots to publication. Additional confirmatory ballots will only occur where TC 215 decides it is required by exception.
- **Matters considered at the CAG 02 (Coordination Group) meeting (and noted by CAG 01) included:**
  - Frequency of CAG 02 meetings and role of CAG 02 in review of new work item proposals. It was decided that CAG 02 should attempt to meet at least 6 times per year to perform its coordination and review functions more effectively.

    Meetings would be held at each of the two face-to-face TC 215 meetings (as at present), plus once by teleconference about 6-8 weeks after each face-to-face meeting and once by teleconference about 4-6 weeks before the next one.

- Progressing the adoption of planning frameworks for working groups, modelled on the work of WG 3 and WG 6 to assist in planning future work and assessing proposals for new standards development work. Each work group spent at least one session on strategic planning and consideration of the needs and application of a consistent framework.

  Planning frameworks are to be progressed between TC 215 meetings for review on CAG 02 teleconferences and at the next TC 215 meeting.

  [Each work group spent at least one session on strategic planning and the development and application of an appropriate framework.]

- **CAG 02 – Updates on use and governance of SKMT (Standards Knowledge Management Tool)** within TC 215 and the wider health informatics SDO community. Heather Grain spoke to a report on SKMT and learning from usage of an updated prototype of the SKMT by Norbert Sigmond (WG3), noting the issues found and the importance of others actually using the tool and give feedback on any issues.

  The report contains a comprehensive list of identified issues, which are now being actioned by the development team at Sherbrooke University in Canada. Feedback is being sought on the priorities for further work, along with further work to accelerate the delivery of required improvements.

- **Update on JIC activities** – notably work on the Patient Summary Standards Set (PSSS) work. See the notes on WG 1 below for further information.

- **The calendar for future TC 215 meetings** is:

  - 6-10 November 2017 - Liverpool, England (BSI), joint CEN/TC 251
  - 30 April – 04 May 2018 – Maringá City, Paraná State, Brazil (ABNT)
  - **Oct/Nov 2018 – replacement host being sought!!**
  - 13-17 April 2019 – Gothenburg, Sweden (SIS)
  - Oct/Nov 2019 - Korea (KATS), Daegu. Dates & location tbc.
  - **2020 – Hosts being sought for both Apr/May and Oct/Nov**

- **Olympics Healthcare Interoperability (OHI) initiative**. This activity is being spearheaded by Mike Nusbaum on behalf of HIMSS, the JIC and its members. An overview of the concept and recent progress was presented in the leadership forums, the JIC, with a more detailed presentation coverage in joint meetings reported under WG 2 below.

- **Potential liaison with ISO/TC 307 Blockchain and distributed ledger technologies**. The potential for such a liaison was referred to WG2 for comments, it is relevant to TC 215/WG 2 work on interoperability of systems and WG 2 are considering a preliminary work item on Blockchain in health.

- **Change of ISO/TC 215 Secretariat**

  Ms Diana Warner took over the role of TC 215 Secretariat from Lisa Spellman in February 2017.

  ISO/TC215 expressed its appreciation to Lisa for her dedication, significant contributions and years of service as ISO/TC215 Secretariat.

	At the time of this meeting, the TC 215 Secretariat was also supporting WG 2, WG 3 and WG 4 (as well as TC 215 itself) and had one staff member about to take maternity leave. It was noted that this is not sustainable and was one of the reasons that a subcommittee structure had been proposed for consideration. WG 1 has also had no secretariat, but it was confirmed that this will now be provided by SIS (Sweden).

WG 1 Architecture, frameworks and models.

Across all sessions, around 14 delegates from 8 member countries participated in core WG 1 activities (excluding experts who only participated in joint sessions) – the total attendance across in joint sessions was several times that in the core attendance.

Meetings took place in 9 sessions over 3 days. Richard Dixon Hughes participated in most WG1 sessions including the break-out group that worked on patient registries. The following matters were noted:

- **WG 1 Secretariat**. Anette Eriksson of SIS (Sweden) had taken over the role in February but she was unable to be present in Hangzhou for this meeting.
- **WG 1 Convenor**. Stephen Kay (UK) had announced that he would not be nominating as convenor. It was noted that the TC 215 Secretariat would called nominations for a replacement after the meeting.
  Subsequently, Mr Björn-Erik Erlandsson from Sweden was nominated and was approved by TC 215 ballot as the next WG 1 convenor.
- ***ISO/PRF TR 19669 Health informatics -- Re-usable component strategy for use case development*.**
  - Revised draft prepared following Lillehammer meeting and then confirmed by CIB in March 2017
  - Updated draft was in process of being submitted to publication
  - ISO/TR 19669 methodology had been successfully trialled on the JIC PSSS project with favourable outcomes being reported.
- **Edition 2 of *ISO 13606 .. EHR Communication (EHRcom) - Parts 1 to 5*.**
  - Following successful incorporation of comments from the earlier CD ballots, ISO/CS released all 5 parts for a 3-month DIS ballot in the week of the Hangzhou meeting;
  - This limited the potential or need for any detailed discussion of ISO 13606 at this meeting.
- **Planning and evaluation framework for WG1 ("WG 1 Framework")**. There was considerable discussion of an appropriate WG 1 Framework based on adapting the models originally provided by WG 3 (and discussed at CAG 02).
  A simple 2-page depiction of a proposed WG 1 Framework was put forward by the WG 1 Convenor (Dr Stephen Kay) as a straw-man for discussions,

with many suggestions being made for improvements (to be incorporated through subsequent iterations after the Hangzhou meeting). A "mission statement" would be added and a tabular presentation of scope elements against consumer-focussed assessment criteria would be attempted with a view to completion at the next face-to-face meeting in November 2017.

The WG 1 planning session also discussed the CAG 01 request for all WGs to consider potential TC-wide reorganisation to a subcommittee structure rather than the current WG configuration. Pros and cons were identified but WG 1 felt it needed more information about the intent before coming to any conclusion.

- ***ISO/NP TS 22287 Workforce roles and capabilities for terminology and terminology services (Term Workforce).***

  In joint session with WG 3, experts from WG 1 agreed this was a useful work and suggested that material on codes of conduct and practice should be included.

  The value of WG 1 doing a similar and joint exercise with WG 3 on the Information/terminology cross-over workforce was noted (for consideration in light of the final WG 1 Framework).

- **ISO/PWI on *Quality management requirements for patient registries*.**

  The question of a standard on quality criteria for patient registries had been introduced at the November 2016 meeting of TC 215 in Lillehammer, with agreement that Peter Goldschmidt (US) would lead a task force to develop the concept. The types of registries potentially covered include:

  1 Public health reporting registers - Ebola, zika, births, deaths.

  2 Clinical registries – Tracking the care and health of individuals. These are typically managed by specialist societies to evaluate outcomes of treatments for disease and/or clinical procedures.

  3 Drug and device registers - for clinical trials etc.

  4 Regulatory drug & device registries. E.g. some FDA approvals require all patients using drug/ device to be registered.

  The goal of the project is to publish an ISO standard that specifies quality management (QM) requirements for patient registries. These requirements are primarily intended to be used by patient registry stewards (PRS) to guide the governance, design, implementation, operation, and evaluation of patient registries, and potentially, by accredited certifying organizations, to determine if a PRS is meeting such requirements. The standard is proposed to supplement, constrain and elaborate on the application of ISO-9001:2015, Quality management system in the context of patient registries. Beyond addressing the collection and production of data and continuous quality improvement, the standard is expected to encompass stakeholder needs, interoperability (through standardization), data security, confidentiality, and informed consent. The work may facilitate the development of professionally run registry services and increase the confidence of regulators in accepting and trusting registry information.

  This work is of potential interest to Australia, and RDH is an active member of the project team, which met and crafted a draft scope and PWI resolution,

resulting in TC 215 approving a ISO/PWI on *Quality management requirements for patient registries* being added to the WG1 work plan.

Further participants are welcome to join the project team and contribute to the production of the Form 4 for NP ballot.

- ***ISO/NP 22272 DTR .. Methodology for enterprise business and information management needs analysis to support standards-based architectures***.
  - Project lead (PL) Jessica Rosenälv reported on progress
  - Part of the original Swedish document on which this work is based had been translated into English
  - WG 1 requested the PL now engage with the drafting team and that extracts of the translated work be circulated for consideration
  - Translations of parts 1 and 2 is to be completed and circulated, prior to presentation at the November 2017 TC 215 meeting in Liverpool.
- **Edition 2 of *ISO 12967 Health informatics – Services architecture (HISA) - Parts 1, 2 and 3*.**
  - The project leads (PLs) were unable to attend this meeting,
  - Slides on progress with Part 1 and the plans for Parts 2 and 3 were presented by Dr Stephen Kay on behalf of the PLs
  - WG 1 noted the progress being made but were concerned at the delay in Part 1 being ready for CD ballot
  - WG 1 also indicated some concern at the amount of work being done without wider engagement - this will be raised with the PLs
  - The plan continues to be that all 3 parts will be eventually published together;
  - RDH and Dr Zoran Milosevic are nominated Australian experts on this project;
  - Australian work on *SA HB 137-2013 E health Interoperability Framework* (eHIF) and *SA HB 138-2013 E-health architecture principles* (eHAP) informs Australian input to the project.
- ***ISO/DTS 18864 Health informatics - Quality metrics for detailed clinical models***
  - Ms. Sun-Ju Ahn reported on the DCM metrics work, noted that the document had passed DTS ballot, and presented a revised document and disposition of comments
  - The TC 215 Secretariat had confirmed that *ISO/DTS 18864* could proceed to publication, without any further resolution being required
  - WG 1 supported the revised document going forward to publication and congratulated Sun-Ju Ahn.

- ***HL7 EHR-Functional Model profile for Immunisations***
  - Gary Dickinson (GD) presented new HL7 work on this topic, noting that it has now progressed considerably
  - GD encouraged international involvement, extending an invitation for anyone interested to join the HL7 project
  - The increasing difficulty of ISO and HL7 collaborating formally on development of joint publications was noted; nevertheless, input from the ISO/TC 215 and/or national experts would be valuable.
- **TC 215 Ad Hoc Group on Health Informatics for Aging Communities**

  This item is reported further under observations on WG 2 (below).

  The interest of WG 1 in this work and the previous contribution of WG 1 to work on *ISO AWI 18:2016 Framework for integrated community-based life-long health and care services in aged societies* was noted. WG 1 will continue to track the work, although it is still somewhat unclear what contribution health informatics standards can make at this time.
- ***ISO/TS 21667:2004 .. Health indicators conceptual framework***
  - Given previous Australian involvement and adoption of this work, RDH was reminded that he has still to investigate potential Australian support for update following systematic review - and report back to the next TC 215 meeting.
- ***ISO/DTS 21089 .. Trusted end-to-end information flows***
  - This WG 2 project is a normative update of material first published as *ISO/TR 21089:2004*.
  - In early 2017, TC 215 approved publication of the updated draft as a TS following a 4-week confirmatory CI ballot.
  - The document has yet to be published and its current status remains somewhat unclear – with formatting issues possibly needing to be resolved with ISO/CS before final publication.

- **JIC Patient Summary Standards Set (PSSS) project**

  The current status of the JIC Patient Summary Standards Set (PSSS) project was presented and discussed in joint session of WG 1 and WG 2, with discussion being led by Elizabeth Keller, Don Newsham, Dr Stephen Kay and Mike Nusbaum. Jane Millar of SNOMED International (SNOMED-I), the project coordinator was an apology due to her commitments to the SNOMED-I Business Meeting being held in London the following week.

  As described in more detail in the report of the Australian delegation to the November 2016 TC 215 meeting in Lillehammer, the aim of this work is to identify and document a **Standards Set relevant to a particular use case** for a shared patient summary, **along with recommendations for national and international use**. The work aims to identify the relevant standards

and their application, not to produce a separate standard – although it has been recognized that such standards sets might subsequently form the basis of a reference standards portfolio (RSP) standard within TC 215 and/or other SDOs.

The PSSS project work is organised under four task groups:

Task group 1. Detailed use case development (Elizabeth Keller)

The agreed use case focusses on an emergency presentation for COPD.

A clinically focused group was responsible for drafting the use case - building on the TC 215 ISO 19669 Use case standard, and the completed data element set and initial full draft of use case from the INTERPAS (IPS) and Trillium Bridge collaboration.

This was substantially completed at a meeting of the task group in January.

During discussion, Malcolm Clarke (UK) asked whether consideration was given to the reviews of the UK GP2GP program which indicated that summaries on a shared central EHR repository are rarely accessed and what clinicians really need is shared access to full records. Elizabeth Keller responded, indicating that the data quality issue from the UK trials had been noted - this exercise had been kept simple to actually get to a result – in many cases, the desirable information is simply not there – but if it is, then clinicians need a way to know it's there and to get what they can.

Task group 2. Standards identification and analysis (Don Newsham)

Responsible for the standards categorization approach and developing the template for a JIC Standards Set, with the goal of determining:

> *"a coherent collection of standards and standards artefacts that support a specific Use Case"*

It has involved two major activities:

- Determining the potential list of standards that "MAY" be applicable in the Patient Summary Standards Set;
- Assessing the list of standards against a per-determined criteria for inclusion in the set of standards.

It has been necessary to keep this as simple as possible and recognise that there are alternate standards available (for additional, specific requirement or future use). The output comprises tables of standards that are likely to be updated over time.

Task group 3. Conformity Assessment (Michael Nusbaum)

The key deliverable is a two-part report that describes:

1. A Conformity Assessment **Framework**
2. Conformity Assessment **Artefacts** supporting a Patient Summary Standards Set

The task group is currently working through issues to ensure the commentary aligns with advice from ISO/CASCO:

Task group 4. Implementation guidance document development (Stephen Kay):

The aim of the implementation guidance is to help people to find the parts of the documentation most relevant to their needs and to provide “down to earth” guidance on “leading practice” at this point in time and how to incorporate governance, maintenance, and feedback from lessons learned into standards-based solutions. It is not attempting to be an implementation guide but, rather, a guide to implementation at a particular point in time.

The guidance addresses four types of intended audiences – decision-makers, developers and standards developers, vendors, consultants and currently addresses 12 topics (including “regulatory factors” and “tooling”). Suggestions for other topics are welcome.

Overview of timeline for completion

- Content finalized – end of May 2017
- JIC review – end of June 2017
- Target audience review – August 2017
- SDO signoff – JIC face-to-face meeting in Liverpool, November 2017.

WG 2 Systems and device interoperability

WG 2 meetings took place in 9 sessions over 3 days. Across all sessions, a total of around 50 delegates from 8 member countries and 6 liaison organisations participated in WG 2 activities (including experts who participated in joint sessions). The average recorded attendance was 28.6 experts per session.

Richard Dixon Hughes participated in some WG2 sessions. The following matters were noted:

- **Current strategic themes for WG 2 work:**
  - Collaboration and coordination with other WGs, external initiatives, and standards organisations
  - Reference Standards Portfolios (Clinical Imaging in the first instance & potentially also others)
  - Medical devices – ISO/IEEE 11073-series, Ophthalmic instruments, Laparoscopic & endoscopic interventions
  - Aging communities and assisted living
  - Genomics/Omics – Omics Markup Language, Whole Genome Sequence Markup Language
  - Olympics Healthcare Interoperability (OHI) initiative and EHR interoperability
  - Interoperability – particularly the BRIDG Model, HL7/FHIR and DICOM/Clinical Imaging

- **Olympics Health Interoperability (OHI) initiative.**

  Mike Nusbaum gave presentations to CAG 01 and to WG 2 on the status and progress of the Olympics Health Interoperability (OHI) initiative - with the following being noted:

  - The activity is now a HIMSS initiative with active support from SNOMED International, JIC, HL7 International, IHE International, and GS1
  - The aim is to demonstrate how the use of appropriate standards can advance the seamless exchange and use of health information throughout the Olympic community (and thereby progressively enhance the capabilities of the Olympic ecosystem and demonstrate the value of relevant standards).
  - Need to work within the current Olympic healthcare IT model – and the relevant Olympic sponsor organisations – including GE (medical services, Centricity), Atos (from Spain, provider of the registration & identification system) - along with health services and systems donated to the various teams and contracted health service provider organisations in each of the host countries. One of the over-arching Olympic goals is to leave improved health infrastructure as a legacy.
  - The initiative will develop capability progressively – starting with the Japan 2020 Summer Olympics. The outcomes will be incorporated into the relevant Olympic handbooks and technical manuals.
  - The approach is based on working through use cases selected by the various stakeholders and validated via connectathons.
  - Initial effort will focus on two use cases: (1) Athlete collapses with cardiac event on track – information needs to be on hand; and (2) Relative of athlete in crowd collapses due to abdominal pain.
  - The Olympics represents an opportunity to support an integrated, multi-national, multi-disciplinary, multi-vendor healthcare environment servicing a multi-national patient population comprising tens of thousands of athletes and officials, upward of a hundred thousand of volunteers and millions of spectators.
  - Those interested in participating are invited to contact Mike Nusbaum.

- ***ISO DTR 21835 Clinically relevant data which a person generates daily***
  - On recommendation of WG 2, TC 215 approved the project being re-named: ***"Health-related data which a person generates daily"***
  - Status and update on progress was provided by Prof. Joon Hyun Song, and Prof Il Kon Kim (Korea)
  - NP ballot passed in October 2016 (with CA, RU, SE, UK against) and was discussed at previous TC 215 meeting in Lillehammer;
  - Updated draft was not available for discussion in Hangzhou;

- Comments and questions indicated some continuing concern over the utility of the work and need for it to have true international focus.
- When available, updated draft to be circulated as a WD in time for comments to be provided for consideration at the November 2017 meeting in Liverpool and possible approval for DTR ballot;
- RDH is the nominated Australian expert.

- ***ISO/DTR 20055 .. Person-owned document repository for PHR applications and health information exchange***
  - Status and update on progress was provided by Byoung-Kee Yi (Korea)
  - DTR ballot closed 8 April 2017 and passed (13 approving, 1 against (FI) and 16 abstentions) and 50 comments to address;
  - Comments need to be addressed and timelines and actions for agreeing final copy and proceeding to publication confirmed;
  - As the DTR ballot passed, once the comments have been addressed the document may be published without any further resolution.
  - The Australian My Health Record system is one of the examples cited in this broad review of the field.
- ***ISO/NP TR 20841 .. Trans-national health record***
  - Status and update on progress was provided by Il Kon Kim (Korea)
  - NP ballot passed in September 2016 (with CA, RU against); and was discussed at previous TC 215 meeting in Lillehammer;
  - Project is to produce a draft that is acceptable for DTR (CD) ballot. There does not seem to have been significant progress.
  - The rationale for the scope of this work, which includes cancer screening, new-born screening and general health checks as parts of the record, continued to be challenged in discussions.
  - WG2 resolved that this activity should be synchronised with other related activities – the JIC PSSS, HL7 International Patient Summary (IPS), the OHI Initiative and the EU eStandards Roadmap.
  - Dr Andy Bond, Corey Monaghan (QH), Stephen Oluyide (Vic DHHS) and RDH are the nominated Australian experts.
- ***ISO/PWI TR 22228 .. Healthcare applications of blockchain technologies***
  - TC 215 approved this PWI being added to the WG 2 work program at the November 2016 meeting in Lillehammer.
  - Project lead, Byoung-Kee Yi (Korea), gave a presentation summarising
    (1) the nature of blockchain and distributed ledger technologies;

(2) healthcare issues potentially addressed by the technology;

(3) results of preliminary survey of potential healthcare applications;

(4) outline of initial suggestions for healthcare applications – virtual health records using FHIR resources & API's; authenticating e-prescriptions; high-integrity randomised clinical trials; and facilitating secure, private EHR-PHR data exchange;

(5) the main sections in the proposed TR;

(6) plans to have a draft for issue to NP Ballot at the November 2017 TC 215 meeting in Liverpool;

(7) inviting interested participants to contribute through a Google Group by contacting him at byoungkeeyi@gmail.com.

- During discussion, the importance of tracking the work of IS0/TC 304
- Potential Australian contributors should contact, IT-014 Chair, Richard Dixon Hughes (richard@dh4.com.au)

- ***Proposal for ISO/PWI on: Structured clinical gene fusion report in electronic health records***

  - A/Prof Soo-Yon Shin (Korea) presented his proposal for a PWI to be put on the WG 2 work program to address this topic, noting:

    (1) the importance of capturing structured data elements and metadata to describe the full range of mRNA molecular measurements (transcriptome information) - including from other species (including viruses and bacteria);

    (2) the proposed document will describe report guidelines for whole transcriptome and targeted RNA sequencing approaches;

    (3) it will focus on detecting novel and known fusion partners;

    (4) it will define the required data fields and their metadata for a structured clinical transcriptome sequencing report and, also, the optional data fields and their metadata;

    (5) it will cover the fusion gene from human samples using whole transcriptome sequencing by next generation sequencing technologies for clinical practice; and

    (6) this work will complement DNA-level reporting structures specified in ISO/TS 20428:2017 Health informatics -- Data elements and their metadata for describing structured clinical genomic sequence information in electronic health records.

  - The potential for collaboration with the HL7 Clinical Genomics WG and to implement structured report using HL7 FHIR Genomics profiles was noted.

- ***ISO/PWI 17583 .. Terminology constraints for coded data elements expressed in ISO harmonized data types used in healthcare information interchange (Binding)***

  - In joint session of WG 3 and WG 2, the Project Lead, Ted Klein, raised a series of important strategic questions about developments in the field and the need to consider these before the direction of work on *ISO/PWI*

17583 and decisions about the actions to be taken on the related *ISO 21090 .. Harmonized data types* standard can be progressed.

- These issues will be canvassed further among the two WGs and in relevant forums (including HL7 and SNOMED International) with a view to proposing the most appropriate direction for the proposed work on *ISO/PWI 17583* at the November 2017 meeting in Liverpool.

- ***ISO/NP 21860 .. Reference standards portfolio for clinical imaging (RSP-CI)***
  - A progress report on behalf of the project team was given by Dr Anna Orlova (with apologies from Project Lead, Kevion O'Donell of DICOM, who had been unable to attend the Hangzhou meeting)
  - DICOM has led the initial spadework on extending the draft, with a discussion at HL7 in January
  - The comments received from the NP vote in September 2016 were reported to have been reviewed and addressed
  - The aim is to have developed a further draft and socialised it with DICOM and nominated experts by September for approval to go to CD ballot at the November 2017 TC 215 meeting in Liverpool
  - Consideration may also be given as to whether to move this work directly to DIS ballot, rather than a CD ballot
  - Richard Dixon Hughes and Dr Peter MacIsaac are the nominated as Australian experts on the *ISO 21830* project but have yet to be contacted by the project leader.
- ***ISO/NP 23042 Health informatics - Information models - Biomedical Research Integrated Domain Group (BRIDG) Model version 5.0***
  - BRIDG Version 5.0 is a significantly enhanced version of the BRIDG model, jointly developed by CDISC and HL7 International, where it has been the subject of simultaneous balloting.
  - Enhancements include clinical genetics content, references to DICOM, and coordination with DICOM to avoid duplication of content.
  - On recommendation of WG 2, TC 215 approved *ISO/NP 23042* being put to NP ballot with a view to the document agreed by HL7 and CDISC going directly to DIS ballot for ISO endorsement.
  - Interested members of the TC 215 community were encouraged to participate in the development and balloting of the underlying BRIDG v5.0 standard through HL7 and/or CDISC, in order to make the product more acceptable when it comes to TC 215.
  - *ISO/NP 23042 BRIDG v5.0* is being balloted independently and not as a revision to *ISO 14199:2015 .. Information models -- Biomedical Research Integrated Domain Group (BRIDG) Model* (Ed. 1)

- ***ISO/PWI 22218 Common Specification for output data of Ophthalmic Examination Equipment***
  - On recommendation of WG 2, TC 215 approved the project being re-named: **"Ophthalmic examination device data"**.
  - Akihiro Harada and Tomoya Obama of the Japan Ophthalmic Instruments Association (JOIA) reported on the status and progression of this PWI, item, which had been approved by TC 215 in Lillehammer.
  - The proposed areas to be addressed by this document were outlined – to be the first part in a series of three standards (comment- the numbering should be changed to reflect this).
  - The standard will use concepts from JOIA Standards – already accepted by IHE International Eye Care Committee as a standard for interoperability of ophthalmic testing equipment (for which 60% of global supply comes from Japan).
  - This part will address standardised reporting of refractive measurements, intraocular pressure measurement and lens power measurement.
  - Next steps:
    (1) working draft (WD) and Form 4 to November 2017 TC 215 meeting in Liverpool to consider for potential ISO/NP ballot;
    (2) Best case – updated WD ready for CD ballot after April 2018 meeting in Brazil.
  - Comment: HL7 CDA r2 is being considered as the preferred reporting medium; should the project be encouraged to consider providing the information using a FHIR representation?
- ***ISO/NP 21393 .. Omics Markup Language (OML)***
  - An update on the progress of this project was presented by Prof. Michio Kimura for Jun Nakaya (Japan).
  - His presentation included an outline of the scope of the standard, with more detail about what aspects are in scope and what is out of scope – the focus is on XML schemas for reporting of Omics-phenomena related to human health.
  - The current draft is substantially complete, is 174 pages in length, and is ready for circulation and consideration prior to being put up for CD or DIS ballot at the November 2017 TC 215 meeting in Liverpool.
  - The presentation has clarified that this document is headed for an international standard (and not a TR or TS as sometimes reported).
  - This project collaborates with the CDISC BRIDG group, HL7 FHIR genomics group, and the WHO ICD iCOS group.
  - Australia should also encourage collaboration with ISO/TC 276 Biotechnology.

- ***ISO/NP TR 25720 .. Whole Genomic Sequence Markup Language (WGSML)***
  - An update on the progress of this project was presented by Prof. Michio Kimura for Jun Nakaya (Japan).
  - His presentation included an outline of the scope of the standard, with more detail about what aspects are in scope and what is out of scope.
  - the focus is on XML schemas for reporting of whole genome sequence (WGS) information related to human health.
  - The current draft is substantially complete, is 127 pages in length, and is ready for circulation and consideration prior to being put up for DTR ballot at the November 2017 TC 215 meeting in Liverpool.
  - This project collaborates with the CDISC BRIDG group, HL7 FHIR genomics group, and the WHO ICD iCOS group.
  - Australia should also encourage collaboration with ISO/TC 276 Biotechnology.
  - According to the presentation, this document is headed for an ISO/TR (and was approved as such at NP ballot); however, given that it is a substantive piece of work of a normative nature, is Ed 2 of ISO 25720:2009, and parallels ISO/NP 21393, which is headed for an IS, the Australian position should be to support its development as an IS.
- ***ISO/PWI 22227 .. Laparoscope/Endoscope Intervention***
  - On recommendation of WG 2, TC 215 approved the project being re-named: ***"Endoscopy and related data"***
  - Professor Nakajima from Osaka University gave a presentation on developments in endoscopy (including moves toward surgical usage), the explosion in endoscopic data and the importance of standardization.
  - Whilst interchange formats have largely been standardized, the technical terms and coding schemes used in the process of "reporting" endoscopic procedures have largely been left to vendors, the standard will seek to address these issues and also define rules for description
  - The standard(s) will propose use of currently existing standards e.g. HL7 CDA R2, DICOM, wherever possible and appropriate.
  - Japanese involvement is supported by METI funding
  - A Form 4 and working draft for ISO/NP ballot are proposed to be available for consideration at the November 2017 TC 215 meeting in Liverpool.
- **Proposal for an ISO/PWI on: *Reliability assessment criteria for high-throughput gene-expression data.***
  - Dr Leming Shi (China) gave a presentation entitled *"Toward Precision Medicine Quality Control and Standardization in Genomics and Bioinformatics"*

- The presentation convincingly highlighted problems driven by the lack of agreed methods to assess the reliability of high-throughput gene-expression data and the processes used to produce such data.
- The proposed PWI within WG 2 would work toward specifying measures for assessing the reliability of high-throughput gene-expression data, to address:
  (1) the accuracy, reproducibility and comparability of gene-expression data generated from microarray, next-generation sequencing, and other forms of high-throughput technologies around the world.
  (2) human health associated species such as human, cell lines, and preclinical animals - other biological species are outside the scope
  (3) expression profiles of all genetic sequences including genes, transcripts, isoforms, exons, and junctions -with genes as the main focus of the proposal.
- Potential areas of application for such a standard include:
  (1) Laboratory proficiency testing
  (2) Quality control - To assess sample quality and batch effect
  (3) Identifying best practice in end-to-end RNA-seq processes best practice
  (4) Specifying quality metrics for RNA-seq data analysis
- TC 215 approved the recommendation of WG2 that a PWI be added to the WG 2 work program to progress a work item in this area.

- **ISO/NP TS 22077-4 Medical waveform format Part 4: Stress test electrocardiography**
  - Following a successful NP ballot, which closed in February 2016, Satoshi Kobayashi (Japan) has been preparing a WD (working draft)
  - This project is in risk of running out of time unless the WD is ready for consideration and approval to go to CD ballot at the November 2017 TC 215 meeting in Liverpool.
- **ISO/PWI 22077-5 Medical waveform format Part 5: EEG**
  - Koichiro Matsumoto of the MFER (Medical waveform Format Encoding Rules) Committee reported on the status and progression of this PWI, item, which had been approved by TC 215 in Lillehammer.
  - The scope of the work is proposed to include:
    (1) Electroencephalography as performed measured in hospitals, neurophysiological laboratories and clinics.
    (2) Various types of electroencephalography such as sleep polysomnography examination (PSG), brain death determination, evoked potentials (EP) and electromyography (EMG)
    (3) Potentially, other related waveforms.
  - The proposed work is the fifth in the ISO 22077-series, which embody MFER approaches to the encoding of other medical waveforms.

- It was noted that use of 22077-encoding does not preclude the possibility of encoding the same waveform using other approaches and that the work will progress in consultation with experts on the European Data Format (EDF) standards and advance standardization in the field.
- Next steps:
  (1) explanation of details and recruitment of experts in at November 2017 TC 215 meeting in Liverpool
  (2) production of working draft and Form 4 for NP ballot for approval before, or at, the April 2018 TC 215 meeting in Brazil.

- **ISO/PWI on: *Reliability assessment criteria for token-based document sharing***
  - Satoshi Abe (Japan) presented briefly on this topic.
  - TC 215 approved the recommendation of WG2 that a PWI be added to the WG 2 work program to progress work in this area.
  - Further information is not presently available in the meeting records.
- **Strategic approach to genomics work**
  - Noting that there seem to be a large number of genomics-related topics coming into TC 215, particularly through WG2, Richard Dixon Hughes suggested that ISO/TC 215/WG 2 develop a strategic plan for to address proposed standards work in this field and to ensure that the activities are coordinated and appropriate.
  - This suggestion was accepted by WG 2
  - Any Australian input in this regard that could be taken to the November 2017 meeting of TC 215 would be greatly appreciated.
- **Ad Hoc Group on Health Informatics for Aging Communities**
  - Group Leads Mr. Todd Cooper (US/ANSI) and Professor Il Kon Kim (Korea) reported in a joint session of WG 1 and WG 2 followed by lively discussion and sharing of experiences among many of the delegates.
  - Work is being progressed on a 12-month timeframe with multiple face-to-face meetings of available team members and several out-of-session meetings with potential stakeholders. These include:
    - January 2017 at HL7 San Antonio HL7 WGM (Joint with TC 215 & DICOM)
    - Stakeholder meetings in Korea
    - April 2017 at ISO/TC 215 Meeting in Hangzhou, China
    - August 2017 around IHE Korea Connectathon in Daegu
    - November 2017 around ISO/TC 215 Meeting in Liverpool, UK
  - In accordance with the initiating resolution, it is intended to produce a draft report for consideration at the November 2017 TC 215 meeting in

Liverpool. The proposed outline of the report is currently structured as follows:

1. Outcome of survey of national challenges and activities (with focus on P-Members)
2. Identification of representative use cases/scenarios; business drivers and requirements; and inhibitors
3. Assessment of related technology and standards work
4. Placing this in conceptual framework or model (with a model developed in Korea for support of rural communities providing a potential starting point)
5. Recommendations for TC 215, including the identification of potential RSPs to address key use cases, any other standards work required (noting that most standards should already exist); recommended liaisons with relevant groups; and a Roadmap.
6. Bibliography

- Inputs include IWA 18[2] and, work on supporting aged and aging societies by the Personal Connected Health Alliance (PCHA - incorporating Continua), IEC SyC AAL (Active Assisted Living), JTC1 and others

- There was considerable lively discussion, including the need to recognise the patient/client viewpoint (backed by Ed Hammond anecdotes of personal experiences in using technology to assist in managing conditions while ageing); the broad and diverse nature of both national responses and the areas impacted when looking from the ageing/AAL viewpoint; and the growing but unpredictable impacts of robotics, AI, workforce issues and options for personalised care.

- RDH questioned the prevalence of those from the health sector to regard all subjects as “patients” in this context. He also expressed concerned at potential disconnects between programs for the elderly and others in the community with almost identical disabilities - Not all those who need assistance at home are elderly and not all with needs are necessarily at home – some are in community and/or care settings.

- Malcolm Clarke spoke on his 30 years’ experience as a research engineer providing and evaluating assistive health and telehealth technologies alongside clinicians in the UK.

  In his view, much of the technology already exists but the bigger challenge is integrating the technology and associated systems into clinical and social support workflows. The issue is how to create systems and make the necessary changes to services and roles needed to provide individuals with effective support at home and in the community.

  In the UK, the GP is the gatekeeper (except for ER), but that is different in each country, as are the activities of the other supporting professions,

[2] ISO. IWA 18:2016 Framework for integrated community-based life-long health and care services in aged societies.

their roles and the applicable regulations, which poses a problems for standards-setters.

Research papers can already tell us much on what we can learn – but there is also a lack of relevant papers – too many focus on sensors, and on data/analytics, and not enough on making it work and scale effectively in a complex environment.

- **ISO/IEEE 11073-series of device communication standards**. WG 2 manages ISO fast-track adoption of these standards brought across from IEEE at FDIS stage.

  The current status of the program was reviewed briefly, led by a presentation by Malcom Clarke (UK) in his role as a liaison officer with the relevant IEEE committee.

- **WG 2 Secretary.** WG2 is still seeking its own permanent secretary separate from the TC 215 secretariat.

WG 3 Semantic content

Across all sessions, attendance was fair with 14 delegates from 9 countries and 2 liaison organisations (HL7 and IHE International) participating in WG 3.

More detailed observations and comments on WG 3 activities are presented in the separate delegate report from Heather Grain, convener of WG 3, which has been substantially reproduced as Appendix A to this report.

Attendance at WG3 was potentially affected by the number of experts that were unable to travel to both the TC 215 meeting in Hangzhou and SNOMED International Business Meeting being held in London from 23 to 26 April.

WG 4 Security, Safety and Privacy

Across all sessions, some 24 delegates from 11 countries and 3 liaison organisations (TC 292, CEN, IHE) participated in WG 4 (including 5 that joined remotely by Webex for specific items).

Appendix B to this report includes more detailed observations and comments on WG 4 activities adapted from the separate delegate report from Prof Trish Williams.

Several WG 4 work items are of potential interest to Australia and Australian work on privacy, security and safety in health is also potentially very relevant to several proposed new ISO/TC 215 projects.

Australia continues to contribute information, expertise and significant leadership effort to progress projects underway and proposed on health information privacy.

WG 6 Pharmacy and medicines business

The Australian delegation lacked the resources to participate significantly in WG 6 on this occasion.

Across all sessions, some 36 delegates representing 10 countries and 2 liaison organisations participated in WG 6 (including 10 joining remotely by Webex).

Substantial progress has been made in progressing and completing the IDMP (Identification of Medicinal Products) standards and associated implementation guides – with strong support from the US/FDA and input from ICH and EC/EMA.

As work on IDMP comes to maturity, WG 6 is considering other areas of potential work (within an ethos of keeping the workload manageable).

Australia continues to monitor and contribute where possible to WG 6 activities. Some items reported by WG 6 from this meeting included:

- **IDMP Workshop**. This was again well attended.
- ***ISO 11238*** **(Ed 2) IDMP standard on substances and the associated ISO** ***TS 19844*** **(Ed 3) implementation guide**.

  Work on bringing these documents to ballot within ISO in time to meet urgent implementation deadlines (including decoupling these ballots from parallel ballots in CEN, to avoid delay) was a significant activity for WG 6.
- ***ISO/NP TS 22756 Requirements for a knowledge base for clinical decision support system*****.**

  The proposed TS will specify requirements for developing the content of a knowledge base for use by a clinical decision support system (CDSS), to address questions such as: What are the criteria for selecting a data source for inclusion in the knowledge base? What are the quality criteria for the development and maintenance for the algorithms or clinical rules for drug safety? etc.

  It is proposed that the scope would NOT go to the point of addressing:

  - requirements for the clinical decision support systems that use the content of the knowledge base, combine it with patient data, and presents the outcomes to clinical users; and
  - requirements for knowledge bases other than those related to medication.
- ***ISO/NP 22703 Requirements for Medication Safety Alerts***. Following discussion, WG 6 resolved to recommend to TC 215 that this item could proceed to NP ballot, which was approved.
- ***ISO/DTR 20831 .. Medication management concepts and definition***. A total of 193 comments were received in the DTR ballot. Updated version revised to accommodate comments was approved for publication.
- ***ISO/DTR 14872 ..Core principles for maintenance of identifiers and terms*** (in joint session with WG3). Reconciliation of comments continuing with view to following relevant WG3 documents relating to review and

maintenance of terminology and code-sets. Many authorities are already addressing the need for mappings between existing identifiers and those used with IDMP. Project lead (Vada Perkins) working on draft for approval at the November 2017 meeting.

- ***ISO/DTS 19293 Requirements for the record of dispense medicinal products***. A total of 167 comments were received from the DTS ballot, many of which were persuasive. The comments and feedback have demonstrated considerable variations in dispensing practices in different jurisdictions. Time is running out to complete the work. The next draft will proceed to publication following internal ballot of WG6 experts.

JWG 1 Joint ISO/TC 215 - ISO/TC 249 WG: Traditional Chinese Medicine (Informatics)

Across all sessions, 16 delegates from 4 countries and 1 liaison organisation were reported to have participated in the meetings of JWG 1.

Across all sessions, some 14 delegates from 4 countries and 1 liaison organisation were reported to have participated in the associated meetings of the Traditional Medicines Task Force (TMsTF). It is understood that all meetings of JWG 1 and TMsTF were run as joint meetings.

Australian coverage of the JWG 1 and TMsTF meetings was limited to the joint session with WG 3

JWG 7 Joint ISO/TC 215 - IEC/SC 62A WG: Safe, effective and secure health software and health IT systems, including those incorporating medical devices

Across all sessions, some 37 attendees from 9 countries and 2 liaison organisation participated in the meetings of JWG 7. A total of 3 sessions were held with WG 4 (Security, Safety and prvacy). with all sessions being held jointly with the Traditional Medicine Task Force (TMTF).

Appendix B to this report includes more detailed observations and comments on JWG 7 activities adapted from the separate delegate report from Prof Trish Williams.

Australia continues to contribute information, expertise and significant leadership to progress JWG 7 work, particularly through the efforts of Prof. Trish Williams and Dr Vince McCauley.

Key items/actions for Australia:	Australian experts and delegates continue their commitment to work on key TC 215 projects including: • *ISO 12967 Health informatics – Services architecture (HISA) Parts 1, 2 and 3, Edition 2.* • *ISO/NP 21860 .. Referenced standards portfolio for clinical imaging (RSP-CI).* • *ISO 17115:2007 .. Vocabulary of compositional terminological systems.* • *ISO/CD 17117-1 .. Terminological Resources, Part 1: Characteristics.* • *ISO/DTS 21564 .. Terminology Resource Map Quality Measures (MapQual).* • *ISO/PWI TS 22287 Workforce roles and capabilities for terminology and terminology services (Term Workforce).* • *ISO/DTS 21526 .. Metadata repository requirements in healthcare.* • *ISO 13120 .. Syntax to Represent the Content of Healthcare Classification Systems - Classification Markup Language (ClaML), Edition 2* • *ISO/PWI on Healthcare Terminology Implementation Capability and Maturity Models - Part 1: Capability (TICMM-1)* • *ISO/IEC 80001-series and JWG 7 work on health software safety and risk management* • The ISO/TC 215/TF 1 survey of quantities and units in e-health. • Convening of regular WG 3 teleconferences to progress WG 3 work items between TC 215 meetings (HG as convenor of WG 3). • PWI developing the proposal for a standard on requirements for patient registry • Providing advice to ISO/TC 215/WG 1 on any required revision of *ISO/TS 21667:2004 .. Health indicators conceptual framework*, noting that this was the subject of an identical adoption as an AS in 2012. (RDH would welcome input on this topic). IT-014 continue to approach relevant stakeholders to raise awareness and seek feedback on Australian activities and interest in areas relating to the following current TC 215 products and projects: • The new *ISO/PWI TR 22228 Healthcare applications of blockchain technologies* [contact Richard Dixon Hughes] • *ISO/DTS 21564 .. Terminology Resource Map Quality Measures (MapQual).* [contact Heather Grain] • *ISO/PWI TS 22287 Workforce roles and capabilities for terminology and terminology services (Term Workforce).* [contact Heather Grain] • *ISO/DTS 21526 .. Metadata repository requirements in healthcare.* [contact Heather Grain]

- *ISO/TS 21667:2004 .. Health indicators conceptual framework* – and any actions in relation to the Australian identical adoption: *AS 21667-2012* [contact Richard Dixon Hughes].
- *ISO 12967 Health informatics – Services architecture (HISA) Parts 1, 2 and 3, Edition 2* [contact Richard Dixon Hughes].
- *ISO 25237:2017 Health informatics - Pseudonymization.* – and any actions required in relation to *ATS ISO 25237-2011*, the Australian adoption of the previous *ISO/TS 25237:2008* [contact Richard Dixon Hughes].
- *ISO/IEC 80001-series and JWG 7 work on health software safety and risk management* [contact Trish Williams].
- Approved PWI on *Application of previously management to personal health information* [contact Trish Williams].
- Finding Australian representatives willing and able to advise and, if possible, contribute on areas of emerging interest and innovation within TC 215 and the global health informatics community, such as: genomics/omics, big data analytics in health, mHealth, applications of wearables & implanted devices, aging society. [contact Richard Dixon Hughes].

Other issues that need to be addressed by IT-014 in conjunction with the wider health informatics stakeholder community include:

- Actions in relation to the Australian identical adoption: *AS 21667-2012* of the *ISO/TS 21667:2004 .. Health indicators conceptual framework*.
- The future of *ATS ISO 25237-2011* in light of *ISO 25237:2017 Health informatics - Pseudonymization* and whether there is support for a further direct-text Australian adoption.
- Australian adoption of *ISO/DTS 20428 and other ISO genomics/omics standards* - it is suggestion of th*is* should be deferred until the documents are at the level of full ISO standards as part of a broadly accepted TC215 strategy for work on genomic/omics standards.

  At the Guangzhou meeting, Australia suggested that ISO/TC 215/WG 2 develop a strategic plan for proposed standards work in genomics/omics (noting that there seem to be a large number of ad-hoc work items being put forward). This suggestion was accepted and any Australian input for the November 2017 meeting would be greatly appreciated.
- continue to consult with relevant Australian organisations and experts to consider justification and, where appropriate, arrange for preparation of project proposals for AU adoption of relevant TC 215 standards publication, notably:
  - *IEC 82304-1:2016 Health software -- Part 1: General requirements for product safety*
  - *ISO 21667 Health informatics - Health indicators conceptual framework (Ed.2)*, updating the existing adoption AS 21667-2012.
  - *ISO/IEC 80001 series (Application of risk management for IT-networks incorporating medical devices)* – as part of its current revision.

	- *ISO 12967 Health informatics – Services architecture (HISA)* - Parts 1, 2 and 3 (Ed. 2) • Engaging with the broad range of stakeholders involved with the supply, regulation and use of medication and pharmaceuticals in relation to both IDMP and the on-going work of TC 215/WG 6. Other matters of potential interest to some Australian stakeholders may include: • **Activities of Ad-Hoc Group – Health informatics standards for aging societies** This ad hoc group is identifying the need for TC 215 standards work to support the health informatics needs of ageing communities. Such work seeks to bring together mobile, wearable, smart-home, cloud-based, knowledge-driven CDS, data analytics, IoT, AI, and EHR/PHR technologies to improve the economy, effectiveness and quality of life in aging societies. Work is already underway but Australian participation would still be welcome. • **WG 1 Ad-Hoc Group on clinical registries.** Work is already underway and more Australian participation would be welcome. • **Developments in the application of IDMP standards** for identification of pharmaceutical products and medicinal products in regulatory and clinical research environments. • **Participation in the Olympics shared heath record initiative** (see WG 2 report above). • More active role for CDISC/BRIDG standards in Australian clinical research.

Status of the work:	The status of most noteworthy work items is reported under the "observations and comments" for the related working group(s), and includes comments provided in the delegate reports presented as Appendices to this report. A schedule of recent and current TC 215 ballots (and their closing dates) as at the date of this report is provided as Appendix C below. Other items approved for ballot but that have not yet appeared on the ISO ballot site or Appendix C, and therefore potentially needing to be addressed in coming months, include: • NP ballot for: *ISO 17115:2007 .. Representation of categories, constraints and associations between categories needed to express terminology (CatStructure)*. [Project lead – Heather Grain]. • Proposed early systematic review of *ISO 17090-4:2014 .. Public key infrastructure – Part 4: Digital Signatures for healthcare documents* to produce Ed 2 incorporating pdf signatures. [WG 4 project].

Recent & pending ISO/TC 215 publications (since November 2016 meeting)

- *ISO/TS 16843-1:2016 Health informatics -- Categorial structures for representation of acupuncture -- Part 1: Acupuncture points*. Published 2016-11.
- *ISO/TS 18062:2016 Health informatics -- Categorial structure for representation of herbal medicaments in terminological systems*. Published 2016-12.
- *ISO 21549-7:2016 Health informatics - Patient healthcard data - Part 7: Medication data* (Ed 2). Published 2016-12.
- *ISO 25237:2017 Health informatics – Pseudonymization*. Published 2017-01. Needs to be reviewed for potential Australian adoption – and any actions required in relation to *ATS ISO 25237-2011*, the Australian adoption of the earlier *ISO/TS 25237:2008.*
- *IEC/TR 80001-2-9:2017 Application of risk management for IT-networks incorporating medical devices -- Part 2-9: Application guidance -- Guidance for use of security assurance cases to demonstrate confidence in IEC/TR 80001-2-2 security capabilities*. Published 2017-01.
- *ISO 21298:2017 Health informatics - Functional and structural roles*. Published 2017-02 (corrected 2017-03).
- *ISO/IEEE 11073-10417:2017 Health informatics -- Personal health device communication -- Part 10417: Device specialization -- Glucose meter* (Ed 3). Published 2017-04.
- *ISO/TS 20428:2017 Health informatics -- Data elements and their metadata for describing structured clinical genomic sequence information in electronic health records*. Published 2017-05
- *ISO/TR 18638:2017 Health informatics -- Guidance on health information privacy education in healthcare organizations*. Published 2017-06.
- *ISO 17090-5:2017 Health informatics -- Public key infrastructure -- Part 5: Authentication using Healthcare PKI credentials*. Published 2017-07
- *ISO/TR 20831:2017 Health informatics -- Medication management concepts and definitions*. Published 2017-07.
- *ISO 12052 Health informatics -- Digital imaging and communication in medicine (DICOM) including workflow and data management* (Ed 2). Published 2017-08.

Suggestions for Australian adoptions are welcome and, in the first instance, may be raised with Richard Dixon Hughes, Chair IT-014 (richard@dh4.com.au) or with Katalin Veres (Katalin.Veres@standards.org.au), the IT-014 project manager.

	The following have been approved and submitted for publication but are yet to be published. • *ISO/PRF TR 19669 Health informatics - Re-usable component strategy for use case development.* • *ISO/IEEE 11073-10101:2004/Amd 1 Additional definitions*. • *ISO/IEEE 11073-10422 Health informatics -- Personal health device communication -- Part 10422: Device specialization -- Urine analyser*.

Other stakeholders:	In addition to the IT-014 membership (which includes ADHA, jurisdictions, HISA and ACHI) the following are noted as having potential interests in the projects indicated: • AIHW and the SA mirror committee to JTC1/SC32 (Data management and interchange) regarding ISO/DTS 21526 Health informatics, Metadata repository requirements in healthcare, which extends ISO/IEC 11179 to include metadata required for use in health. • ACHI and HIMAA regarding engagement in the ISO/PWI TS 22287 (Term Workforce) project. • HE-003 in relation to software safety and associated medical device topics. • HE-031 for issues related to traditional medicine • HE-003, ACSQHC, TGA and AIHW regarding potential interests in medical device and health software safety issues and • TGA and ACSQHC regarding IDMP for pharmaceutical regulation.

APPENDIX A – REPORT* ON THE MEETING BY HEATHER GRAIN (CONVENER ISO/TC 215/WG 3)

* Abridged & edited in places for this appendix.

INTERNATIONAL DELEGATES MEETING REPORT

Date	22 April 2017
Name	Heather Grain
Position/Title	Managing Director
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Purpose of Meeting	The purpose of the TC 215 meeting was to progress the work program and to review potential new projects in the field of health informatics, including joint work with other ISO and IEC technical committees. In relation to WG3 (Semantic content), where Heather Grain is the Convenor, this includes reviewing and developing strategy on the development of standards required by national members to advance semantic content in health informatics.
Key items discussed	**CAG 2 Coordination Meeting** The framework for standards work produced by WG3, along with the procedure for framework development and use was discussed extensively. Each work group was requested to prepare their group's version for further discussion. SKMT: the It was agreed that there is a requirement for all work items from ISO to have data entered into SKMT prior to going for final publication. Presentation given by Heather Grain on issues identified in trial and at Lillehammer Plenary. All members requested to review and indicate priorities and when using the tool to report issues/errors found. Ask JIC – SKMT governance committee to consider relationships to other common definitions published by other organisations such as IEEE (HG will take this to the SKMT Governance Committee). Work Items coming forward were discussed to identify needs for harmonised input and activity.

CAG1 Executive Council and Operations Meeting

Strategic Business Plan

- CAG2 will review all new project proposals to identify mutual interest between WGs and harmonise the approach to standards production.
- CAG2 to meet at the end of the work group meeting so that this discussion can happen as soon after the plenary as possible then one to prepare for the plenary.
- The structure of the TC was discussed and issues associated with use of subcommittees vs work groups was discussed. The ballot issues that allow sub committees can ballot their own resolutions. This may be an issue for harmonisation. Having subcommittees meeting separately is an issue, particularly in ensuring attendance and obtaining financial support.
- Outcome may be change but at last will be the documentation of the requirements for health informatics standardisation and the pragmatic approach to appropriate solutions.
- The end state may be a hybrid of Working Groups and Sub Committees.

Liaison Reports

- Internal ISO Liaisons have been reviewed to determine which liaison's we will be actively engaging with. The decision was made that we do not actively engage with any of these committees, though we would like to the resources are not available to do so. In this case the liaison is from the internal ISO committee to our committee rather than bidirectional. The only bidirectional currently is TC249 In each case those we do not actively engage with will still have access to our documents etc
- A call with liaison's will be arranged

Ageing communities

- Todd Cooper reported on activities in Shanghai recently, and the important relationships to TC249. This will be discussed further during the meeting in joint sessions.

Traditional Medicine WG

- TC249 has an established informatics and terminology work group (WG5). An efficient and effective method to handle the need of TC249 which are not explicitly Chinese Medicine fall outside the scope of joint work, these projects fall within TC215. There is a lot of work in this area and the most effective way to handle this to reduce duplication and ensure harmonised approaches are maintained to deliver quality standards.

International Health Informatics Standardization Forum

TC215 Contributors

Mike Glickman – Chair of TC215 spoke on the scope and objectives of TC215.

Ted Klein – HL7 explained the approach of HL7 and how that organisation works collaboratively and openly to develop standards. Indicating that government, software developers, academia all work together to achieve outcomes with all players on an equal footing. The objective being to find the agreed core shared requirements to reduce cost of development while encouraging diversity of function and utility of software products. The different HL7 products - V2, CDA and FHIR, where described.

Bron Kisler – CDISC and convenor WG2 spoke on the rationale for development of CDISC indicating the broad support that now exists for standardised representation of data for clinical research and trials. These standards allow less time to be spent on development of research projects and data specification and more effort on analysis of the data collected. There is also the advantage that data from different studies are able to be compared thereby improving the ability to mine different research material as well as different conventional national data collections.

Heather Grain – Convenor WG3 Semantic Content – Described the framework of standards development for meaning representation in health care. The presentation identified risks and issues which arise from thinking simply of code systems, rather than what the code systems are intended to do. The specific standards work being undertaken was summarised. There is a strong movement to standardisation of concept representation in China and there was considerable interest in how to reduce the risks identified. Particular standards in development in which there was great interest included: Quality of data specification
Christian Hay - GS1

Presentation on the place of GS1 in identification of products and devices through bar codes and RFID. The use of these standards in supply chain was explained and the particular relationship between these services and the standard – Identification of Medicinal Products (IDMP).

Todd Cooper – Olympic Healthcare Interoperability Initiative. This initiative seeks to leverage the requirement of Olympics to leave behind advances and improvements with the local infrastructure by using a standards based approach to healthcare records and activities at Olympic games. This work leverages learnings from Rio Olympics and is working actively with the Olympic committees for the upcoming winter and summer games. The mission of the project is to ‘’advance the seamless exchange and use of health information, using established international standard to support an integrated medical service infrastructure at each Olympic Games site. The OHI network connects

pre-Games person-specific healthcare information with information generated at Games time by Olympic and Host City Service providers.

The objectives of the project are to increase the efficiency and effectiveness of the Olympic medical services functional program through the integration of interoperable healthcare information technology. Also to demonstrate to the world that the international adoption and implementation of standards-based interoperable healthcare information technology directly impacts:

- Better healthcare of the Olympic population, athletes, coaches, staff, volunteers, family and spectators.
- Improved health outcomes through availability of, and secure access to appropriate information at the right place, audience and time.
- Reduction of total time for diagnosis and treatment
- Reduction of waste of human and system resources
- Improved care coordination, quality, safety efficiency, and population health.

Plenary – Tuesday Q1

Welcome from officials from Hangzhou, Standards Administration China, and Department of Family and Health Planning – China. The Chair updated the plenary on the business strategy, and CAG1 and CAG 2 meetings from the previous day.

Working Group 3

Attendees at WG3 included the following 9 countries and 2 liaison organisations, represented by 14 contributing individuals

- Australia
- Canada
- China
- Germany
- Japan
- Korea
- Ireland
- United Kingdom
- USA

Liaisons:

- HL7 International
- IHE International

Working Group 3 – Tuesday Q2
DTS 21564 Health informatics, Terminology Resource Map Quality Measures (MapQual)

Ballot reconciliation was undertaken. The meeting agreed that the document was nearing completion. Discussion occurred on the comment that the document does not reference significant academic evidence for what is proposed. It was agreed that this is not required as such evidence does not yet exist and the proposed approach is the best practice available from expertise from many countries. The document contains determinants which will be normative in the TS, and an informative set of minimum quality requirements for specific use cases.

The use cases are to be expanded to show the impact and decision making process appropriate to map use and maintenance.

The work group were strongly supportive of this process. And some members have trialled the process suggested. It is intended that this document will be updated, completed and distributed to the WG by September with the intention to finalise in time to be distributed to NMBs before the Liverpool meeting with the hope that it will go forward for DTS ballot after that meeting, and hopefully be published in 2018.

This work item requires input from Jurisdictions, ADHA, AIHW.

Heather will prepare a web presentation on this work item to update the community and make it openly available. Link is at: http://www.gehco.org/standards-projects/mapqual

WG 3 Tuesday Q3
ISO/TS 21526 Metadata Repository Requirement in Healthcare (MetaReq)

A draft of this document will be available after this meeting. Some known issues include

- How the continuum of data is managed in metadata repositories to enable consistent local data specification and automation of aggregation and mapping for reporting.
- Will include simplified versions
- FHIR resource metadata will be included
- Concept systems specification both for classification and for terminology binding
- Working draft includes value sets and domains
- Relational models will reference 19763-12
- Forms and document metadata (will reference 19763-13)
- openEHR Archetypes
- Schema models – where does that go in the metadata – may be a new work item for WG2
- Mapping – 19763-13 is working on a general approach
- Include information on metadata for registration of data usage (not just data sets which use the data). This work needs to be a stronger process than a simple subscription.

Draft will be circulated to the WG with the intention of a document ready for CD ballot request in Liverpool.

Heather will prepare a web presentation on this work item to update the community and make it openly available. Link is at: http://www.gehco.org/standards-projects/metareq

Meeting jointly WG3/WG1 – Tuesday Q4
ISO/NP/TS 222287 Workforce Roles and Capabilities for Terminology and Terminology Services (Term Workforce)

This work item has passed NP ballot.

The work will be expanded to include data managers, clinical data professionals, terminology governance etc. The titles of the roles are not seen to be appropriate and need to be clarified.

The intention is to take the broad range of comments, ensure that scope is not limited to the view of Health Information Managers only. The expert group, which includes Heather Grain will work on this document, prepare a draft document for discussion in detail in Liverpool. This document is hoped to be ready for CD ballot after Liverpool.

Additional actions associated with this work will be WG1 will consider the development of a partner document on workforce roles and capabilities for Information Mapping in Healthcare. It was also suggested the WG3 consider a next stage document which provides guidance on curricular content and course certification.

This work may be of interest to ADHA. HIMAA and ACHI and their comments would be welcome.

Heather will prepare a web presentation on this work item to update the community and make it openly available. Link is at: http://www.gehco.org/standards-projects/termworkforce

Joint WG2 and WG3 – Wednesday Q1
ISO/NP 21860 Reference standards portfolio for clinical imaging (RSP-CL)

Document presented by Anna Orlova (USA). Disposition of comments on NP proposal document. Clarification of content was requested and will be addressed. Inclusion of content associated with HL7 products such as FHIR to also be incorporated. Diagrams will be updated to include XDS-I to better show the relationship of this format.

ISO/PWI 17583 Terminology Constraints for Coded Data Elements

This project focuses on binding. Work is evolving at HL7 and this work includes updates of Coded Data Types. The issue of whether binding should be to value set expansions or to value set definitions.

The 21090 data types work is primarily used by CDA which does not use the binding requirements. FHIR has different, simpler binding strengths which are not compatible with 17583 original work nor with the ISO/HL7 coded data types. The use of the concepts of binding strengths – required, extensible, preferred and example. The benefit of FHIR is the development of standards on rapid development prototyping concepts is proving highly valuable. This work item may evolve into a 'bundle' approach rather than a new standard at ISO.

This will be further considered in Liverpool meeting.

BRIDG V2, CDISC-HL7- joint CDISC0HL ballot and next steps, BRIDG NWIP

Bron Kisler reported on the public review of BRIDG v5.0 (cdisc.org

The BRIDG imaging Project scope will include harmonised with key concepts in DICOM to support interoperability. Imaging use cases. The focus is on DICOM to BRIDG mapping to support common use cases. It is scoped to include computer tomography.

Majority of the elements from the identified DICOM model already exist in BRIDG. 14 new semantic classes were added to BRIDG because of harmonisation focusing on modelling-by-reference. Bridge will point to DICOM where relevant and DICOM will point to bridge where relevant. They will not be duplicated.

Joint WG 3 and WG6 Wednesday Q2
prEN ISO/DT14872 Identification of medicinal products (IDMP) – core principles of maintenance of identifiers and terms

Proposed as a TR. The purpose of this work is to describe the proposed maintenance model and core principles for implementation of the ISO IDMP standards.

Core principles include high level points to consider when assessing an organisation's ability to provide IDMP terminology maintenance services.

Specific terminology requirements are described in IDMP Technical Specifications – and there is a need to incorporate the evolution in thinking based upon the processes needed to support the IDMP TS Annexes.

Minimum set of core principles for terminology maintenance and distribution are unique to regulators and bio/pharmaceutical industry due to data owner constraints. This work will be harmonised with and inform the PWI proposed on terminology governance and quality assurance which WG3 is considering.

This work will be based upon existing TR from WG3 about terminology governance organisations and have adopted what was practical. This work will define what is expected of those developing terminology content for medicinal products. There is also a need to move into the future to consider safety alerts and recalls and manufacturing issues.

WG3 suggested that a future piece of work should also include the development of specific map quality assessment for maps used in pharmaceutical practice. This proposal was received well and would provide information which could be used to update the existing WG3 TS.

There is a need to get Australian Therapeutic Goods Administration input on this document for the future as well as ADHA input.

Requirements for Decision Support using Knowledge Base.

This is a potential new work item specific to pharmacy domain. Decision support for pharmaceuticals should include a range of input attributes such as diagnosis, age, pharmaceutical information etc. rules upon which the decision support are based upon, and this proposal is about how to develop the relevant rules to support computer decision support. The process should, for example, address national, international guidelines, standardised data structure, and relevance of maps will be important. What people or systems develop and determine the rules. Who should establish the algorithm and process. It should be transparent. Once a rule is made it should be transparent etc.

The existing Australian Guideline on Clinical Decision Support was explained to the group and is sought as a useful underpinning document. A copy of this work should be sent to the convenor of this committee.

Requirements for Medication Safety Alerts

This is being proposed as a potential new work item with more information coming forward in Liverpool.

This work item can also be informed by both the Australian Guideline on Clinical Data Support, and on User Interface Requirements. It is recommended that a copy of these be sent to Christian Hay, the convenor of this working group.

Working Group 3 Wednesday Q3
ISO/CD/IS 17117-1 Health informatics, Terminological Resources, Part 1: Characteristics (TermChar)

This work item describes many of the complex concepts associated with terminological resources of all types. It serves as an excellent reference point when describing such systems and their capacity.

This work item will come forward as a DIS ballot after this meeting.

The document will now clearly differentiate between the functions that the characteristics of a terminology may deliver and those which are required to achieve certain types of terminological resources.

Question on what is an atomic concept a code system may include axiomatic concepts as well as compositional concepts required for different use cases. The role – role relationship mechanisms were more clearly defined.

All comments were approved. This item will go forward as a DIS ballot after this meeting.

ISO 17115:2007 Health informatics, Vocabulary for Compositional Terminological Systems

This work will be a major revision of the existing publication with the intention to include the European standard on Categorial Structures. This work item has been led by Heather Grain and Prof. Hirose (Japan).

The document will extend relevant definitions associated with categorial structures but not repeat the definitions relevant to mapping work, nor those in 17117 unless they are relevant to the document. It will reference 17117 as a normative reference.

Resolution for title change:

Representation of categories, constraints and associations between categories needed to express terminology (CatStructure)

Heather Grain will prepare a draft of this new work by the end of April for circulation to WG3 members with the intent of circulation to the TC NMBs prior to Liverpool. It is hoped that this will progress to DIS ballot after Liverpool.

Working Group 3 – Wednesday Q4

ISO/IS 13120:2013 Health informatics, Syntax to Represent the Content of Healthcare Classification Systems - Classification Markup Language (ClaML)

Minor modifications were applied to better cope with national variations. This work item will go forward as DIS ballot from this meeting.

SKMT report

HG presented a report on the trail of SKMT and actions intended. WG3 agreed that project leaders of work items going to ballot will be entered into SKMT. WG3 agreed that 17117 and MapQual details will all be entered or updated to SKMT between this meeting and the next.

It is intended that the SKMT Governance Committee will be discussing the issues and priorities. WG3 prepared it's priority

Working Group 3 – Thursday Q1

ISO/PWI Health informatics, Healthcare Terminology **Implementation Capability and Maturity Models - Part 1: Capability (TICMM-1)**

Now to be converted to

- 17115–2 Terminological Resources part 2 – Implementation Requirements (TermIR)
- 17115–3 Terminological Resources part 3 Implementation Maturity Models and Measures (TermIMMM)
- 17115–4 Terminological REsources Part 4 Quality Assurance

Working Group 3 – Thursday Q2

New Proposal – graphical symbols in Health – not discussed as project leader not here and

ISO/PWI Health informatics, Time Standards for Healthcare Specific Problems (N489-WG3 European Standard EN12381:2005)

New Development Cycle
ISO/PWI/DTS Health informatics, Value Set Definition Design and Governance

This area of work is the next highest priority of WG3 after the implementation requirements work in the 17117 series.

There is significant work occurring in HL7 on definition, It seems relevant to reference HL7 work in a bundle and develop the missing pieces within WG3. Emerging information will be helpful and governance in HL7 can inform the governance part of this process.

Work which could potentially be included in a bundle includes HL7 standard for trial use - Characteristics of a Formal Value Set Definition (release 1) published june 2016 focus is on operationalising the value set definition. In September, we have the objective of moving it to normative. The key piece is the business purpose of the value set. If you change the purpose you change the item and require a new identifier. The harmonisation of this work with ISO activities in MetaReq and 17117 will be needed.

Bundles needed for terminology might include:

- Bundle for implementation and use
- Bundle for developers of terminologies and classifications
- Bundle for governance of terminology

The committee agreed to produce a list of components for a terminology bundle/s (RSP) – such a list would include:

- 17117, part 1, part 2, part 3
- HL7 Characteristics of a Formal Value Set Definition
- MetaReq
- Value Set Definition, Design and Governance
- Preliminary work item – Bundle for Terminology
- Mapping
- Workforce
- Value set expansion
- Conformance assessment of data specifications

	The document does not need to wait for completion of all documents for a bundle to be of use. It is intended that documents available will be referenced and those still in development will be indicated to encourage **Conformance Assessment of Data Specifications or EHRs** Anna Orlova will follow up to indicate what the scope of such work could be. This is for further discussion by the WG.
Key Items/Actions for Australia	**Recent ISO/TC 215/WG 3 publications suitable for Australian adoption/ adaptation include:** None at this meeting
Status of the work	• Indicated under the report of each work item Ballots expected prior to the next meeting: **DIS Ballot - ISO/CD/IS 17117-1 Health informatics, Terminological Resources, Part 1: Characteristics (TermChar)** **DIS Ballot - ISO/IS 13120:2013 Health informatics, Syntax to Represent the Content of Healthcare Classification Systems - Classification Markup Language (ClaML)**
Other Stakeholders	In addition to the re-formed members of IT-014, it is suggested that potential recipients of this report include: • ADHA • AIHW and the IT-000 mirror committee to ISO/IEC JTC1/SC32 Data management and interchange, in relation to extensions to ISO/IEC 11179 metadata for use in health. • ACHI and HIMAA regarding workforce project

APPENDIX B – REPORT* ON THE MEETING BY Prof TRISH WILLIAMS

* Abridged & edited in places for this appendix.

INTERNATIONAL DELEGATE'S MEETING REPORT

Date:	5 May 2017
Name	Patricia (Trish) Williams
Position/Title	Professor of Digital Health Systems
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Purpose of meeting:	• ISO/TC215 WG/JWG work item progression, and new work item proposals. This include work items being jointly developed by IEC and ISO. • Many of the items under discussion have direct relevance to Australia and therefore need Australian input and monitoring, and are being worked on by Australian experts. It is also important to provide feedback to the ISO TC215 mirror committee IT-014

Meeting attendees:	Attendance at WG 4 (Security, safety and privacy) and JWG 7 (Safe, effective and secure health software and health IT systems, including those incorporating medical devices) included: Australia, Brazil (on Webex), China, Germany, Ireland, Italy, Japan, Malaysia, Republic of Korea, Netherlands, Russian Federation, Sweden, Switzerland, United Kingdom, USA. Activities undertaken by Trish Williams included participation in a pre-meeting of the JWG 7 leadership team on Sunday 2017-04-16.

Key items discussed:	• ISO/IS 81001-1 "Foundations": the progress of the Concepts & Continuous Process (across technology life cycle) sections, and the collaboration with WG4 on the security aspects • ISO/IS PWI 20429 Health informatics, Principles and guidelines for protection of personal health information being withdrawn and replaced with new PWI: Application of privacy management to personal health information. WG4 is seeking interested contributors. • PWI – TR: Guidance for an identification and authentication framework of networked personal health devices. WG4 is seeking interested contributors. • ISO/PWI TR 21332 Cloud computing considerations for health information systems security and privacy. Title change; no substantive progress; and 8-Week NP Ballot approved. • ISO TS PWI 20405 Framework of Event Data & Reporting Definitions for the Safety of Health Software. Approved for 8-Week DTS ballot.

	• Harmonization proposal for Integrating the Healthcare Enterprise (IHE) Audit Trail Node Authentication (ATNA) Integration Profile ISO 27789 Audit Trails for electronic health records • Ongoing work as detailed below.

Confirm net benefit to Australia in participating:	• The work in WG4 and JWG7 is relevant to Australia given the continuing focus on medical device security and safety. • The work on ISO 81001, revision of 80001, and the input to other security standards is vital for Australia given the increased interest by the healthcare providers and responsibility of the infrastructure providers to give more assurances of security and patient safety.

Observations & comments:	<u>General</u> <u>Opening Welcome</u> • Welcome from China Dignitaries including representative on behalf of Hangzhou Municipal Government - highlighting the desire to create a 'whole of' population for health care system using smart health care supervision and big data for research, administration, clinical care, public health, training and. This will provide an overall quality improvement in healthcare. • China National Institute of Standardization – welcome to Hangzhou and thanked the Hangzhou Digital Health Bureau in organizing this meeting. China is willing to work with colleagues in standardization internationally, and highlighted the important work that ISO TC215 does. • Strategic actions – given that Standards is too difficult for one organisation alone to manage the improved shared collaboration with JTC1 and other standards organizations is an important pressing need for ISO TC215. Accordingly, the 11 Liaison organisations have all posted reports for this meeting, available on the ISO website. <u>ISO Task force reports</u> • Strategic Business plan has been approved • Quantities and Units in eHealth TaskForce convened. Survey was posted (Thanks to Richard Dixon Hughes for his work on this, and Vince McCauley on this Task Force). The survey will be open for a further two weeks. www.surveymonkey.com/r/F77TDNX • Aging Communities (Todd Cooper) and the impact of health informatics has suggested. This initiative tis discussed further below, under JWG7. <u>Joint Initiative Council</u> • Patient Summary Standards Set (PSSS) final draft completed. Contribution to this work by Australian has been through Trish Williams and Vince McCauley. <u>ISO Directive Changes</u> • Resolutions to be posted in 48 hours • CIB will be voted on as per other ballots. • Full review of new and updated directives – Webex will be sent out. • Business plan review now required every 3 years

	Resolution 61- OHI • Olympic Healthcare Initiative – important to show the world how interoperability can work. (Mike Nusbaum, Canada leading)
	JWG7 – Leadership • Update on filling the IEC/SC62A co-convener opening left by Sherman Eagles. There are 4 candidates (Toshi, Georg, Peter, and Patty). • Remembrance of Dr. Juergen Stettin
	JWG7 -Mobile App Development PAS 277 (CEN251) • Mobile App development standard NWIP PAS 277(CEN251) has been approved to be a TS. Stakeholders are small organizations that develop apps. The document is a high level, principles and concepts focussed. JWG7 (va Patty Kranz) is liaising to ensure duplication of 82304 does not occur. There is concern about clinical development of apps (for instance by clinicians) and quality control of the app and potential medical use where they do not meet the formal definition of a medical devices. The changes in the EU regarding medical device regulation and the 'app store' as a nosiness entity will impact this. Australia needs to keep abreast of this standard development and the EU regulations relating to Software as a Medical Device.

	JWG7-81001 Foundation Documents to support 80001 revisions
	• 81001-1 proposes to have 2 regional teams to work on the 2 sections and then switch parts of the document. Logistics of meeting times has made progressing the work difficult.
	• Proposal for community supporting "trusted health systems engineering & management"
	  ○ Todd Cooper implemented an 80001 project at a local children's hospital. The issue of obtaining MDS2 information hampered the project, with reluctance to share by the manufacturers with the hospital. The proposed community group needs physicians and health care providers, HIMs, AACC and AAMI involved in generating a supporting community. One Australian State has such a group. Organizations do not want to disclose their security information.
	• Risk and treatment of risk in 81001
	  ○ A number of presentations and discussion on the tenets of risk and understanding risk for 81001 were presented:
	  ▪ Risk categories from the clinical perspective were presented by Vince McCauley(Au) as an ISO/TC 215 Australia/IHE presentation. This included the risk categories encountered, types of risks(under treated or over treated e.g.in Chemo therapy and ,IVF), lack of software to check provided to protocol, common factors terminology mapping.
	  ▪ 82304-1 accepted in Australia.
	  ▪ Phil Raymond presented on AAMI IT Risk Management ROI which may provided the basis for the business case for 80001-1. Free whitepaper is available at http://www.aami.org/productspublications/content.aspx?ItemNumber=4131

- FDA Digital Health presentation by Bakul Patel, and Michelle Jump provided background on FDA and SaMD to be regulated differently than embedded software in order to allow for innovation and faster approvals. The USA 21st Century Cures Act means that some types of software products no longer medical devices in the US. However, the FDA has not yet operationalized this new legislation.

- ISO 14971 update (harm definition and cybersecurity) Pat Baird (USA)
  - There are 8 task teams working on the revision of ISO 14971.
  - Proposed change to the 14971 definition of harm:
    ~~physical~~ injury or damage to the health of people, or damage to property or the environment
    NOTE: Damage to property may include breach of data and system security. Data and system security are defined as the operational state of a medical device in which information assets (data and system) are reasonably protected from degradation of confidentiality, integrity, and availability.
  - Proposed additional guidance for 14971 regarding security: including terminology mapping; adding security-related questions; security priorities balanced with intended use; and differences between safety risk and security risk management as probability/likelihoods are different, human factors trade-offs, security risks are often unrelated to intended use (i.e. a security breach used to access a network does not care what device is used to initiate this access).

<u>WG4 - JWG7 joint work on Risk Management, Security & Privacy (foundation, revision, and definitions) for 81001,</u>

- Tiger team report (Ben Kokx) presented. Outcomes and discussion included:
  - Need consistent set of terms
  - WG4 position is that medical devices cannot be secured on their own and consequently the security of the healthcare environment is the scope of the hospital and therefore the scope of WG4. In contrast Ben highlighted that the medical device manufacturer(MDM) cannot solely depend on the controls of the hospital to secure the device. The MDM is expected to create a product that can operate in many different environments and cannot solely depend on the security provided by the infrastructure. This is expected by both regulators and customers. There is shared responsibility for security and privacy. Responsibility of full system in the hospital, not each device. Each device is responsibility for safety (ISO 14971). Each provider shows their function and if they are meeting HIPPA
  - ISO 14508 common security criteria, there are a number of good security standards out there (industrial control), and MDS2 addresses the minimum
  - Extensive discussion around the separation of responsibility for security between Health Care Organisation (HCO) and MDM.

	• Privacy
	  ○ Vince McCauley (Au) and Trish Williams (Au) presented on the Australian Privacy Principles (13 APPs) as an example of how this might be addressed in 81001. This highlighted the sensitivity of information such as biometric data. The important difference between confidentiality and privacy (data vs person) was made clear.
	  ○ Future consideration for further discussion:
	  ▪ 80001-1 change from data and system security to security and privacy?
	  ▪ Do 80001-2-x 19 security capabilities need to be extended to include privacy?
	  ▪ WG4 is working with JTC1 SC27 WG5 as well as CEN work (TC251) focusing on privacy
	• AAMI new work on security
	  ○ AAMI TIR 97 - post market security will aim to be general and not FDA/USA focused. AAMI SW96 Application of security management to medical devices is a companion to, and the standard that describes, TIR 57
	
	<u>81001-1 – Content development - Process and Concepts</u>
	• Considerable debate on the place of 81001-1 as a standard or a guidance document. Arguably it is a standard because of terminology that we want to re-use and the roles/transition points and as such it is pre-reading for 80001-1. Further discussion when more of the document content has been developed
	• Concepts -Trish Williams (Au): IT & IM Governance, Organizational Culture, Roles and Competencies, System and Software Lifecycle, Safety Management, Change Management, and Socio-Technical Context. The concepts are independent with no cross over between sections of manufacture and implementation lifecycle. This will include work on the socio-technical context (with reference to AAMI HIT 1000). For each concept: a goal, scope, expected measures, resources and guides will be defined.
	• Continuous processes across lifecycle -Michelle Jump (USA) lead: Risk Management, Human Factors, Data Lifecycle, Privacy, and Security. For each process: a goal, scope, expected measures, hand-over specification, resources and guides will be defined.
	• <u>The Australian community is encouraged to participate in this work to capture the extensive experience and knowledge of the Australian community.</u>
	• Terminology also need work to identify troublesome terms with multiple meanings used across the 80001, 81001 and associated standards. Trish Williams will recruit her PhD student Scott Anderson to work on this project.
	• Next step is work planning and drafting before Liverpool meeting.

	<u>JWG7-80001 revision</u> • 80001-1 Process Morphing -Silvana MacMahon (Ireland) Lead • Revision of 80001-1 is based on three main lessons learned to date: a lack of drivers to motivate top management; the healthcare

organizational challenges in IT and BME, which are not aligned; and that 80001-1 is too complicated and complex to implement.

- The proposed approach combines Annex SL structure with use of process assessment standards (SPICE 33000 series). The next step is a new NWIP to select the Process Management activity. Other review of International Certification schemes, ISO/IEC 20000-1 and the relationship between ITSM (IT Service management) revision and status of service model, alignment with ISO 9001, NHS process management approach, will inform the revision approach.

<u>80001-2-x review / incorporation planning - Phil Raymond (USA) lead</u>

- To increase participation and awareness a template "slide deck" will be created to socialize 80001-1 value at conferences. If possible, an ISO website that provides information on JWG7 80001-1 series as for ISO 210. ISO is looking for more TCs to do this.
- EU hospitals will need to certify to ISO 27001 in the future. In Asia, this series is more widely used in enterprise/corporation and not in hospitals. JWG7 should coordinate with 27000 (27799 for healthcare) so we do not put another management standard on the ISO list, and there is value in aligning document formatting and outlines based on the management systems requirement which 27001 also uses.
- Discussion that we should take the security requirements in 80001-1 and map them to existing standard requirements ISO 27000 and ISO 20000 (see below). Instead of the 80001 revisions attempting to integrate security aspects into the standard, it is better to provide the guidance of how all the existing standards might be coordinated aligned and use by an HCO. AAMI is considering writing such a guidance document which might be leveraged. There was agreement that 80001 should not attempt to write their own security standard but provide guidance on the multitude of existing and developing security standards (e.g. mapping).

IEC TR 80001-2-1, Ed. 1.0	2012-07	Revision approved [f]
IEC TR 80001-2-2, Ed. 1.0	2012-07	Revision approved [f]
IEC TR 80001-2-3, Ed. 1.0	2012-07	Revision approved [f]
IEC TR 80001-2-4, Ed. 1.0	2012-11	Revision approved [f]
IEC TR 80001-2-5. Ed. 1.0	2014-12	2018-05
ISO TR 80001-2-6, Ed. 1.0	2014-11	2017-11 [g]
ISO TR 80001-2-7, Ed. 1.0	2015-03	2018-03 [g]
IEC TR 80001-2-8, Ed. 1.0	2016-05	2018-05

- An update security approach needs to be considered and guidance on how to coordinate the use of 2-2, 2-8 and 2-9 and provide info on how they are interrelated. AAMI is working on a similar white paper.
- <u>Trish Williams to talk to her PhD candidate about getting involved in the project and focusing on terminology/vocabulary and joining JWG7 80001 project team (through IT-014).</u> JWG7 members to review project membership list and work with their national representative to put their name on project lists

	JWG7-Ageing • Aging Communities (with IEC SyC AAL): This has a focus of health informatics for aging communities including caregivers (family, friends), and healthcare providers and in collaboration with IEC System Committee Active Assisted Living (AAL). This topic is intended to be across a number of WGs at ISO. They are developing a report specific for aging people, especially focused on people providing services and care. Technology landscape and use; recommendations about which other standards may be needed. Australia already has an IT Aged Road Map (released in June2017) • Given the increased focus on ageing in Australia by local, state and federal government, Australia should ensure it is active in this work from the beginning.
	WG4- ISO TR 11633 Part 1 based on 27000 ISO TS 11633 Health Informatics, Information security management for remote maintenance of medical devices and medical information systems -- Part 1: Requirements and risk analysis • As this item (WG4) is related to medical devices, input from JWG7 was sought to assess cross over with current work. Posted to JWG7 as N342. • Updated document for DTS to be posted by September 18 for discussion at the November Liverpool meeting.
	WG4 NWIP Guideline for authentication framework of the networked smart healthcare devices. • This is an additional framework to the IEEE PHD framework, as the existing uses encryption but does not use authentication and therefore does not address the end to end capability. This work item scope was refined as for connection to public networks (not private networks) and only public internet connected devices, not all medical devices.
	WG4 - N2294 SR: 14441 Security and privacy requirements of EHR systems for use in conformity assessment. • Passed systematic review but multiple clarification updates recommended. Further review and discussion will be held at next meeting in Liverpool.
	ISO 17090-4 Health informatics -- Public key infrastructure -- Part 4: Digital Signatures for healthcare documents. • Early systematic review (due 2019) approved to incorporate PDF signatures.
	PWI – TR: Guidance for an identification and authentication framework of networked personal health devices. • Added to WG4 work program and seeking interested contributors.
	TC292 Liaison. • No update for this meeting.
	ISO/NP 20429 Health informatics, Principles and guidelines for protection of personal health information

	• Resolution to withdraw and replace with new PWI: Application of privacy management to personal health information. New item to be added to WG4 work program and seeking interested contributors. • The new PWI may be of more relevance to Australia than the previous PWI which was deemed unnecessary given the Australian Privacy Principles and other professional guides available
	ISO/PWI TR 21332 Cloud computing considerations for health information systems security and privacy. • Resolution to approve title change change from Cloud computing security and privacy requirements for health information to Cloud computing considerations for health information systems security and privacy. • No substantive progress. Approval for 8-week NP ballot. WG4 seeking interested contributors.
	ISO/PWI TS 20405 Framework of Event Data & Reporting Definitions for the Safety of Health Software. • Finalization of ballot reconciliation - Australian delegation nominated experts reviewed the work prior to DTS. Approved for 8-Week DTS ballot.
	Harmonization of Integrating the Healthcare Enterprise (IHE) Audit Trail Node Authentication (ATNA) Integration Profile ISO 27789 Audit Trails for electronic health records • Carried over from the last meeting, ISO 27789 is due for a systematic review (SR) to align with ATNA to commence earlier than scheduled (2018) DICOM is also being updated and is relevant to this work. • Hideyuki (Japan) will coordinate the review to determine changes and bring report to Liverpool for discussion.

Key items/actions for Australia:	• Australia needs to keep abreast of this standard development and the EU regulations relating to Software as a Medical Device. • The revision of 80001 and development of 81001 is a major initiative internationally. There is increased interest in implementing 80001 in hospitals in Australia and an increasing focus on the security vulnerabilities of medical devices, that 80001 & 81001 can address. It is vitally important that Australia continues to be involved and supported to contribute to this work. • JWG7 Ageing. Given the increased focus on ageing in Australia by local, state and federal government, Australia should ensure it is active in this work from the beginning. • ISO/IS PWI 20429 Health informatics, Principles and guidelines for protection of personal health information. The new PWI may be of more relevance to Australia than the previous PWI which was deemed unnecessary given the Australian Privacy Principles and other professional guides available

	• Many WG4 Security and Privacy work items are seeking additional participation. Australia should do more to engage and support Australian experts to contribute to these standard, and mentor future potential participants, through IT-014 member organisations. • IT-014 requested to approve membership of ISO JWG7 and WG4 for PhD candidate (Scott Anderson) to be involved in 80001/81001 project.

Status of the work:	• JWG7 N334 JWG7 current work program
	  ○ IEC 80001-1 2nd Edition (IEC lead) NWIP approved. (Must have DIS by 10-17-2019)
	  ○ IEC 81001-1 (ISO lead) NWIP approved. (Must have DIS by 9-7-2019)
	  ○ IEC/IS 62304 2nd Edition (IEC lead) CD2 review closes May 26. A project team meeting is planned for June in Austin Texas. CD3 expected to be prepared ahead of next ISO meeting in November.
	• Published documents
	  ○ ISO/IEC 80001-2-9 Confidence case for security capabilities
	  ○ ISO/TC 215 IS 21549-7 Health Informatics- Patient healthcard data-Part 7
	• Sent for publication
	  ○ – ISO/TC 215 IS 25237 prEN ISO/IS Health informatics-Pseudonymization
	  ○ – ISO/TC 215 TR 18368 Health informatics - Guidance on health information privacy education in healthcare organizations
	  ○ – ISO/TC 215 IS 21298 prEN ISO/IS Health informatics-Functional and structural roles
	• Currently in ballot
	  ○ ISO/FDIS 17090-5 Health informatics – Public key infrastructure – Part 5: Authentication using healthcare PKI credentials

Other stakeholders:	• HISA • TGA • MSIA

The following schedule lists ISO/TC 215 ballots that have closed since 01 March 2017 or that are currently open. It does not include ballots that were proposed or approved by ISO/TC 215 but had not opened as at the date of this report. The codes for the types of ballots listed and other abbreviations include:

CD	Committee Draft	CIB	Committee Information Ballot
DIS	Draft International Standard	DTR	Draft Technical Report
DTS	Draft Technical Specification	FDIS	Final Draft International Standard
IDMP	Identification of Medicinal Products	NP	New Project (New Work Item Proposal)
SR	Systematic Review		

The ISO Close Date is the closing date for the ballot at ISO Central Secretariat. IT-014 members are typically required to complete their voting 2 to 3 weeks prior to the ISO closing date to enable any required reconciliation of Australian positions.

Type	Project/reference	ISO Close Date
DTS	ISO/DTS 21564 - Terminology resource map quality measures (MapQual)	2017-03-03
SR	ISO 10159:2011 Web Access Resource Manifest (WARM)	2017-03-06
SR	ISO/TS 14441:2013 Security & Privacy of EHR systems assessment	2017-03-06
SR	ISO/TS 16058:2004 (vers 3) Interoperability of telelearning systems	2017-03-06
FDIS	ISO/IEEE 11073-10101:2004/FDAmd 1	2017-03-09
CIB	ISO/TR 19669 Re-usable component strategy for use case	2017-03-15
CIB	ISO/TS 21089 Trusted end-to-end information flows	2017-03-15
CIB	ISO DIS 11615 .. IDMP – Data elements and structures for the unique identification and exchange of regulated medicinal product information	2017-03-22
CIB	ISO DIS 11616 .. IDMP - Data elements and structures for unique identification and exchange of regulated pharmaceutical product information	2017-03-22
CIB	ISO TS 20451 .. IDMP – Implementation Guide for EN ISO 11616 Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information	2017-03-22
CIB	ISO TS 20443 .. IDMP - Implementation Guide for EN ISO 11615 Data Elements, Structures and Message Specifications for Unique Identification and Exchange of Regulated Medicinal Product Information	2017-03-22
DTR	ISO/DTR 20055 .. Person-owned document repository for PHR applications and health information exchange	2017-04-08
DTS	ISO/DTS 16843-5 - ISO/DTS Categorial Structures - Part 5 Cupping	2017-04-13
	ISO/TC 215 Health informatics meeting – Hangzhou – 17-21 April 2017	
CIB	IEEE 11073-10427-2016 Power Status Monitor	2017-04-29
CIB	Call for Nominations for WG1 Convenor	2017-06-02

Type	Project/reference	ISO Close Date
SR	ISO/TS 16791:2014 .. Requirements for international machine-readable coding of medicinal product package identifiers	2017-06-05
SR	ISO/TS 18530:2014 .. Automatic identification and data capture marking and labelling - Subject of care and individual provider identification	2017-06-05
SR	ISO/TS 21547:2010 (vers 2) .. Security requirements for archiving of electronic health records - Principles	2017-06-05
SR	ISO/TS 22789:2010 (vers 2) .. Conceptual framework for patient findings and problems in terminologies	2017-06-05
SR	ISO/TS 25238:2007 (vers 3) .. Classification of safety risks from health software	2017-06-05
SR	ISO/TS 27527:2010 (vers 2) Health informatics - Provider identification	2017-06-05
SR	ISO/TS 29585:2010 (vers 2) .. Deployment of a clinical data warehouse	2017-06-05
FDIS	ISO/IEEE FDIS 11073-10422 .. Personal health device communication - Part 10422: Device specialization - Urine analyser	2017-06-19
FDIS	ISO/FDIS 17090-5 .. Public key infrastructure - Part 5: Authentication using Healthcare PKI credentials	2017-06-21
NP	ISO/NP TS 22703 Health informatics - Requirements for Medication Safety Alerts	2017-06-22
FDIS	ISO/FDIS 12052 (Ed 2) .. Digital imaging and communication in medicine (DICOM) including workflow and data management	2017-07-06
DIS	ISO/DIS 13606-1 (Ed 2) .. Electronic health record communication - Part 1: Reference model	2017-07-09
DIS	ISO/DIS 13606-2 (Ed 2) .. Electronic health record communication - Part 2: Archetype interchange specification	2017-07-09
DIS	ISO/DIS 13606-3 (Ed 2) .. Electronic health record communication - Part 3: Reference archetypes and term lists	2017-07-09
DIS	ISO/DIS 13606-4 .. Electronic health record communication - Part 4: Security	2017-07-09
DIS	ISO/DIS 13606-5 (Ed 2) .. Electronic health record communication - Part 5: Interface specification	2017-07-09
NP	ISO/NP TS 22756 .. Requirements for a knowledge base for clinical decision support systems to be used in medication related processes	2017-07-12
NP	ISO/NP TR 21332 .. Cloud computing considerations for health information systems security and privacy	2017-07-27
	Approximate date of this report	
NP	ISO/NP TS 22773 ..Categorial structures for representation of decocting process in Traditional Chinese medicine	2017-08-18
CIB	ISO/IEEE 11073-20702 Medical Device Communication Profile for Web Services	2017-08-26

Type	Project/reference	ISO Close Date
DTS	ISO/DTS 20405 .. Framework of event data and reporting definitions for the safety of health software	2017-09-01
NP	ISO/NP TS 21831 .. Categorial structures for representation of processing Chinese materia medica	2017-09-01
NP	ISO/NP TS 22835 .. Categorial structures for representation of combination of Chinese medicine	2017-09-01
SR	ISO/TS 17938:2014 .. Semantic network framework of traditional Chinese medicine language system	2017-09-04
DTS	ISO/DTS 19844 (Ed 3) ..IDMP - Implementation Guide for EN ISO 11238 for data elements and structures for the unique identification and exchange of regulated information on substances	2017-09-06
DIS	ISO/DIS 11238 (Ed 2) .. IDMP - Data elements and structures for the unique identification and exchange of regulated information on substances	2017-09-18
CIB	IEEE/ISO 11073-10424 IEEE/ISO 11073-10424:2014 Device Specialization - Sleep Apnoea Breathing Therapy Equipment (SABTE) Corrigendum 1	2017-09-18
DIS	ISO/DIS 17117-1 Health informatics - Terminological resources - Part 1: Characteristics	2017-09-25
NP	ISO/NP 23042 Health informatics - Information models - Biomedical Research Integrated Domain Group (BRIDG) Model version 5.0	2017-10-06
SR	ISO 1828:2012 Health informatics - Categorial structure for terminological systems of surgical procedures	2017-12-04
SR	ISO/TS 17948:2014 Health informatics - Traditional Chinese medicine literature metadata	2017-12-04
SR	ISO 21549-6:2008 (vers 2) Health informatics - Patient healthcard data - Part 6: Administrative data	2017-12-04
FDIS	ISO/IEEE FDIS 11073-10427 .. Personal health device communication - Part 10427: Device specialization - Power status monitor of personal health devices	2017-12-20

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