ISO/TC 215 operates in the field of health informatics, creating standards for information and communications technology (ICT) in health to promote interoperability between independent systems, to enable compatibility and consistency of health information and data, as well as to reduce duplication of effort.

Health informatics standards developed by ISO/TC 215 are aimed at supporting the growing use of ICT in the health system ("eHealth"). Our standards have a vital role in enabling health information systems to collect information, exchange it seamlessly, and protect its security and privacy, while making it widely available for authorised access by many potential users including health service provider organizations, individual practitioners, funders/payers, regulators, consumers of health services and those that support or care for them.

Even small improvements in the efficiency of health systems around the world provide opportunities for significant payback from investments in eHealth. According to the Global Health Data Standards Charter released by the World Economic Forum in 2011 better health data, which depends on standardization, can improve health outcomes, address disparities, and enable innovation across the health sector.

There are many challenges to effective eHealth standardization that are often in competition with one another, including but not limited to:

- market uncertainty that consensus-based standards truly meet stakeholder needs
- continuous pressure to reduce standards development costs while also bringing new standards to market faster
- proliferation of new eHealth standards for different standards development organizations (SDOs)

These competing demands continue to challenge SDOs to better harmonise and streamline their standardization efforts and outcomes.

This 2016 update builds on a major revision of the plan in 2013 and follows review by a task group which considered changes in the operating environment, assessed the effectiveness of the actions since 2013 and proposed new activities in line with emerging priorities.

ISO/TC 215 proactively maintains many liaison relationships with other ISO technical committees and sub-committees and with many external liaisons including our pivotal role as a founder and host of the Joint Initiative Council (JIC) for Global SDO Health Informatics Standardisation http://www.jointinitiativecouncil.org] formed in 2008 to support harmonisation of eHealth standards among healthcare informatics related SDOs.

Key TC215 priorities for the 2-3 year planning horizon include:

- ongoing and possibly expanded engagement with stakeholder communities to ensure that priorities and activities are relevant and meet stakeholder needs. Such stakeholder targets are elucidated in 2.1.2 Application of ICT within health systems (eHealth)
- continue to actively support intra-ISO and external cross-SDO collaboration on eHealth standardization,
- continued commitment to ongoing improvements in work program management, governance, and rigorous application of the ISO/IEC Directives.
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1. INTRODUCTION

1.1 ISO technical committees and business planning

The extension of formal business planning to ISO Technical Committees (ISO/TCs) is an important measure which forms part of a major review of business. The aim is to align the ISO work programme with expressed business environment needs and trends and to allow ISO/TCs to prioritize among different work items, to identify the benefits expected from the availability of International Standards, and to ensure adequate resources for projects throughout their development.

1.2 International standardization and the role of ISO

The foremost aim of international standardization is to facilitate the exchange of goods and services through the elimination of technical barriers to trade.

Three bodies are responsible for the planning, development and adoption of International Standards: ISO (International Organization for Standardization) is responsible for all sectors excluding Electrotechnical, which is the responsibility of IEC (International Electrotechnical Committee), and most of the Telecommunications Technologies, which are largely the responsibility of ITU (International Telecommunication Union).

ISO is a legal association, the members of which are the National Standards Bodies (NSBs) of some 164 countries (organizations representing social and economic interests at the international level), supported by a Central Secretariat (CS) based in Geneva, Switzerland.

The principal deliverable of ISO is the International Standard.

An International Standard embodies the essential principles of global openness and transparency, consensus and technical coherence. These are safeguarded through its development in an ISO Technical Committee (ISO/TC), representative of all interested parties, supported by a public comment phase (the ISO Technical Enquiry). ISO and its Technical Committees are also able to offer the ISO Technical Specification (ISO/TS), the ISO Public Available Specification (ISO/PAS) and the ISO Technical Report (ISO/TR) as solutions to market needs. These ISO products represent lower levels of consensus and have therefore not the same status as an International Standard.

ISO offers also the International Workshop Agreement (IWA) as a deliverable which aims to bridge the gap between the activities of consortia and the formal process of standardization represented by ISO and its national members. An important distinction is that the IWA is developed by ISO workshops and fora, comprising only participants with direct interest, and so it is not accorded the status of an International Standard.
2. BUSINESS ENVIRONMENT OF THE ISO/TC

2.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal and social dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of this ISO/TC, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards:

2.1.1 Scope of ISO/TC 215

The scope of ISO/TC215 is currently expressed as “Standardization in the field of health informatics to facilitate the coherent and consistent interchange and use of health-related data, information, and knowledge to support and enable all aspects of the health system.”

The Task Group, reviewing this statement, was concerned that the wording did not adequately reflect the work of the Committee in areas such as architecture, information models, semantics, security, privacy and quality. To address this, the Task Group proposed the addition of the word “capture” of data to the statement of scope. The November 2016 ISO/TC 215 plenary meeting in Lillehammer resolved to adopt the following revised scope statement, subject to approval by the ISO Technical Management Board:

“Standardization in the field of health informatics to facilitate the capture, interchange and use of health-related data, information, and knowledge to support and enable all aspects of the health system.”

NOTE: This scope includes items that are also within the scopes of other committees; such areas will be addressed through cooperation including formal liaison relationships.”

During prior discussion of the proposed change with the leadership of IEC/TC 62, it was clarified that:

- The term “health system” relates to the organization of people, institutions, and resources that deliver health care services to meet the health needs of target populations, Wilson and Goldschmidt, WILS1995
- The term “capture” refers to the recording, receipt or delivery of health data

2.1.2 Application of ICT within health systems

The business reference architecture in Figure 1 below (based on ISO/TR 14639:2014) portrays the various components involved in applying ICT effectively to support the delivery and management of health services within a health system. This reference architecture indicates that the development and use of eHealth capabilities within a health system is aimed at achieving the following outcomes:

- Improved quality and safety of care – for both individuals and populations
- Efficiency, productivity and cost effectiveness in delivery of health services
- Improved access to care – particularly for those in remote communities
- Better informed health policy and more effective planning of health services
- Support for evidence-based practice, creation of knowledge and improvement of health services.

As health service delivery increasingly becomes global, services within different health systems also need to be able to interact effectively with each other and exchange health-related data and information efficiently. Health informatics standards are central to meeting this need.

The standards produced by ISO TC215 are important for efficacy in delivering health care and are also very important for safety and security of health information and health IT systems.

The health sector does not live in isolation; it needs to interact effectively with many other domains. These interactions are facilitated by the health sector seeking, as far as possible, to build on general ICT standards and capabilities rather than developing approaches that are unique to the health sector.
2.1.3 Stakeholders

The following are among those with needs to be addressed in the development and use of standards produced by ISO/TC 215 and other eHealth SDOs:

- Developers, suppliers and integrators of health information systems (HIS), applications and services;
- Public / governmental agencies and organisations with broadly-based eHealth programs or responsible for developing and/or implementing eHealth policy;
- Health service provider organizations and clinical practitioners (as users or consumers of eHealth systems and services);
- Health information managers;
- Citizens (patients/health consumers and next of kin) not only in respect of access to individual health information and its security, privacy and safety but also as data providers;

Figure 1: Capacity based eHealth architecture roadmap (ref. ISO TR 14639)
• Those funding, measuring and investing in the provision of health services – including third-party payers, health insurers, NGOs and NFP organizations;
• Clinical and biomedical researchers, the pharmaceutical industry and associated regulators;
• Regulators and certifiers of products and systems supporting delivery of health services;
• The health supply chain providers from original source through to the ultimate consumer of a health-related product;
• Those developing, maintaining and applying terminological resources and knowledge resources for clinical and other health system applications;
• Suppliers of supporting information and communications systems and services including wireless and mobile solutions, medical devices and associated medical technologies;
• Other SDOs and organizations developing standards, specifications and conformance profiles for eHealth.

Along with these, others having an indirect interest in the standards include:
• Academic and research institutions and students in health informatics; and
• Other stakeholders within and interacting with the health sector.

Effective communication with such diverse groups of stakeholders remains one of the major challenges for eHealth standardization, both in terms of production of relevant standards and in communication about the benefits and implementation of eHealth standards.

2.1.4 ISO/TC 215 role in eHealth standards collaboration

ISO/TC 215, along with the European CEN/TC 251 Health Informatics committee, and Health Level Seven International (HL7) established the Joint Initiative Council (JIC) in which the leadership of the member SDOs confer on a regular basis to agree on joint projects and to evolve processes for successful conduct of joint work. Since 2007, the following SDOs have also endorsed the charter:
• CDISC, the Clinical Data Interchange Standards Consortium – admitted 2008. CDISC hosts the Biomedical Research Integrated Domain Group which developed and maintains the BRIDG model for exchange and re-use of clinical trial data;
• IHTSDO, the International Health Terminology Standards Development Organisation – admitted 2009. IHTSDO maintains the internationally recognised SNOMED CT clinical terminology with some 400,000 concepts;
• GS1, the global supply chain and identification SDO – admitted 2010;
• IHE Integrating the Healthcare Enterprise (IHE) – admitted 2012;

While ISO/TC 215 is an equal member, it has a special role under the Charter in that the Charter has a future goal of "making all [joint] standards available through ISO.” ISO/TC 215 provided the first JIC secretariat and most JIC face-to-face meetings are held in conjunction with ISO/TC 215 meetings.

A key challenge for ISO/TC 215 is to be able to offer potential collaborators the ability to publish material speedily and in original electronic formats via ISO processes. ISO/TC 215 has also significant liaisons with many SDOs and other organizations and groups including:
• WHO, the World Health Organization;
• IEEE, in relation to the joint ISO/IEEE health device interface standards;
• ICN, International Council of Nurses;
• IEC/TC 62, Electrical equipment in medical practice;
• IEC/SC 62A, Common aspects of electrical equipment used in medical practice;
• IMIA, International Medical Informatics Association;
• ITU-T/SG 17;
• UN-ECE, UN - Economic Commission for Europe - Edifact etc.;
• Regenstrief Institute;
• PCHA, Personal Connected Health Care Alliance;
• ICH, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use;
• EFMPA, European Federation of Pharmaceutical Manufacturers & Associations;
• HON, Health On the Net Foundation.

It is essential that ISO/TC 215 continue to work with other eHealth SDOs to: develop standards effectively and efficiently; ensure the availability of appropriate and implementable standards that address business, clinical and technical needs; and minimise the multiplicity of standards.

2.1.5 Current trends and issues

For the refresh in 2016, the Task Group identified a number of developments relevant to the work of the committee:

i. a major emphasis on clinical interoperability and greater clinical use of the newest tools, systems, mobile devices and apps for digital health;
ii. a trend for full use of data analytics in transforming, sustaining, planning and supporting the delivery, operation and management of health care;
iii. a move to greater patient participation and personalization in their health care;
iv. a desire to better connect patients, providers and health delivery organizations in the access, scheduling, referral, decision-making and management of patients health and care needs;
v. a need to better manage chronic disease across the entire population;
vi. a drive to continue to transform health care delivery and management to enable a financially sustainable and well-resourced health care system;
vii. mHealth service integration and ageing societies;
viii. the need for competent workforce to support standards development, implementation, operation and use;
ix. garnering participation of stakeholders in the standards development process (voluntary) and making the standards readily accessible to these stakeholders given the high cost for purchase.
x. Internet of Things / Internet of Medical / Internet of Healthcare Things;
xi. Cloud Computing;
xii. Genomics;
xiii. Cyber-security, privacy, security, "malware".

2.2 Quantitative Indicators of the Business Environment

The following list of quantitative indicators describes the business environment in which the TC operates.

The total global health expenditure recorded for 2012 was US$6.5 trillion (http://www.who.int/mediacentre/factsheets/fs319/en/). In most developed countries health care expenditure is a substantial 7-12% of GDP (Gross Domestic Product). Some countries expend considerably more on healthcare, including the USA at around 18% of GDP. For many the percentage of GDP spent on health is growing and this places demands on national budgets and often leads to a desire to achieve improvements through various measures including eHealth.

While eHealth represents only a small part of the overall global expenditure on health services, it is a key enabler in the delivery of more effective health services. In some cases expenditure on eHealth (e.g. telehealth) provides the only means of delivering required health services to those who would otherwise not receive them. By any measure, the global healthcare IT market and associated investments in eHealth are significant, and will continue to expand rapidly for the foreseeable future. For the purposes of this plan, 2013 total global expenditure on eHealth (including government and institutional) was estimated to be in the range US$125 billion to US$150 billion; this represents 1.7% of global health expenditure of US$8,115 billion (as extrapolated from 2010 to 2013).
3. BENEFITS EXPECTED FROM THE WORK OF THE ISO/TC

The measurable benefits of eHealth continue to be debated but the practical reality is that the adoption of new and improved ICT is becoming ubiquitous throughout health service organizations and the wider community. As higher levels of connectivity become available through the Internet, with increased benefits and risks, eHealth standards become increasingly important in opening up access to health information and providing the basis for innovative new technology-based applications.

In its *Global Health Data Charter*, [WEF2011] the World Economic Forum (WEF) identified four key areas of benefits resulting from having better data available through investments such as eHealth. It has been shown that having better health data can:

I. **Improve health outcomes** "Individual health data and population-based data are valuable assets towards optimizing decision-making, which in turn can lead to more effective health management and improved health outcomes."

II. **Address disparities** "Disadvantaged populations have the most to gain from improved health data management, if workforce capacity, technology and investment deficiencies are adequately addressed."

III. **Enable innovation** "Health data can significantly influence transformation by enabling creative thinking and the development of innovative solutions to address our current challenges."

IV. **Drive efficiencies** "Use of health data can deliver increased time and cost-efficiency, resulting in improved productivity and optimized resources."

Health informatics standards developed by ISO/TC 215, where appropriate in collaboration with other eHealth SDOs, have a vital role in enabling health information systems to collect information, exchange it seamlessly, and protect its security and privacy, while making it widely available for authorised access by many potential users including health service providers, individual practitioners, funding organizations, regulators, consumers of health services and those that support or care for them.

Benefits attributable to improved interoperability include improved decision making, and fewer redundant processes, such as unnecessary repetition of diagnostic tests, with the associated risks to patients. Improved interoperability should result in lower overall net cost to the system and improved quality of care. Annex A provides a more detailed exposition and examples of how ISO/TC 215 standards address:

- capture, communication, collection, interpretation and presentation of health information, supporting front-line health care service delivery, individuals in maintaining their own health and wellness, the collection of statistics and comparative measures, public health and biosurveillance clinical research, clinical trials and associated regulatory processes
- systematic definition and representation of health information content to preserve its meaning across applications, to enable its use for secondary purposes (such as clinical research) and to support its safe and reliable use in automated clinical decision support
- interoperability between various health devices and information systems, including enabling the remote delivery of clinical services (e.g. via telehealth services)
- systematic identification of requirements for health information, health workflow, and health information systems functions - providing frameworks for the development and harmonisation of other eHealth standards and specifications.
- the management of risks arising from the growing application of eHealth in the delivery of health services, to ensure information security, to improve clinical quality and outcomes and to protect the safety and privacy of subjects of care

4. REPRESENTATION AND PARTICIPATION IN THE ISO/TC

4.1 Membership

The current P and O membership of ISO/TC 215 may be viewed on the ISO website https://www.iso.org/committee/54960.html

4.2 Analysis of the participation

At the time of preparing this business plan TC 215 had 31 P-members and 29 O-members distributed as follows:

Countries that are P and O members on TC 215 include the major economies from Europe, America, Oceania and Asia as well as some emerging economies and in total they represent between 90% and 95% of overall global health expenditure.

The main gaps in representation and participation on ISO/TC 215 are considered to be:

- Low membership by ISO National Member Bodies across Africa, the Arab world, and central Asian states (exceptions: South Africa, Kenya, Iran, Kazakhstan, Zimbabwe)
- Low and Middle Income Countries (LMICs), noting that some countries active in WHO eHealth activities have yet to become involved in the TC's activities and they should be a priority
- Many of the major corporations developing, implementing and marketing eHealth solutions world-wide are not directly engaged in the work (but some provide input to joint work through other JIC members)

In collaboration with the JIC and other JIC members (notably HL7), the TC has been exploring avenues to reach out to LMICs, particularly in Africa. The experts serving on ISO/TC 215 working groups come from a range of stakeholder groups.
5. OBJECTIVES OF THE ISO/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

5.1 Defined objectives of the ISO/TC215

5.1.1 Introduction

In 2013, ISO/TC 215 adopted the following high-level objectives to guide its activities:

1. make sure that required standards are available to address the needs of the member bodies and stakeholders, by
   (a) prioritizing and co-ordinating the development of health informatics standards
   (b) maintaining a coherent view according to an architectural framework
   (c) harmonizing existing and emerging health informatics standards to establish a global framework of consistent and common standards for health systems and health data
2. adopt or, where identified gaps necessitate original work, develop standards and specifications for health systems design, use and interoperability
3. approve standards
4. with users, review and maintain standards in use to ensure they are fit for purpose
5. provide access and support to all, especially emerging and developing countries.

To realise these objectives, ISO/TC 215 identified a series of actions under the following headings:

- ISO/TC 215 work program
- Structure and scope of ISO/TC 215
- Improved governance and project management
- Engagement with eHealth stakeholder communities
- Cross SDO collaboration on eHealth standardization

Annex B provides a status update on each of the 2013 actions. At the end of each sub-section is a table of numbered actions, either carrying forward “13…” items or proposing new “16…” actions. The refreshed workplan is shown in full in Annex C.

5.1.2 ISO/TC 215 work program

ISO TC/215 will continue to progress its program of standardization to enhance the capture, use and interoperability of health and healthcare information and eHealth systems.

The Task Group (TG) proposed actions to develop an assessment method for ensuring the usability of the committee’s outputs.

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<tr>
<th>Ref.</th>
<th>Action</th>
<th>Resp.</th>
<th>Date</th>
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<tbody>
<tr>
<td>13.04</td>
<td>Investigating improvements to systematic and/or periodic review to ensure standards relevant and fit for purpose</td>
<td>EC + TF(tbd)</td>
<td></td>
</tr>
<tr>
<td>16.01</td>
<td>Develop a method of assessment (quantitative and qualitative) of usability of WG’s products and its implementation</td>
<td>CAG01</td>
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</table>

5.1.3 Structure and scope of ISO/TC 215

The revised structure for the committee has been successfully implemented. As described in section 2.1.1 above, the TG proposed to make a change to the scope statement to reflect the capture of data.
Working Group 3 have been reviewing their way of working and are developing a framework, which may apply to other WGs.

The TG proposed a satisfaction survey on participation by experts in WGs.

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<tbody>
<tr>
<td>13:10</td>
<td>Complete next update of TC 215 BP within 2 years</td>
<td>Committee</td>
<td>?</td>
</tr>
<tr>
<td>16.02</td>
<td>Discuss revised statement of scope with TMB and other relevant committees</td>
<td>EC</td>
<td></td>
</tr>
<tr>
<td>16.03</td>
<td>WG3 to share their framework document with CAG01</td>
<td>WG3</td>
<td></td>
</tr>
<tr>
<td>16.04</td>
<td>Each WG to consider applicability of the WG3 Framework</td>
<td>CAG01</td>
<td></td>
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<tr>
<td>16.05</td>
<td>Finalize the decision and process for a potential split of TMTF from WG3</td>
<td>CAG01</td>
<td></td>
</tr>
<tr>
<td>16.06</td>
<td>Finalize WG3 Framework approach to guide the development of semantic content standards</td>
<td>CAG01</td>
<td></td>
</tr>
<tr>
<td>16.07</td>
<td>Promote a common terminology and definitions through SKMT to give improved governance of use of terms and definitions</td>
<td>WG3</td>
<td></td>
</tr>
<tr>
<td>16.08</td>
<td>Identify gaps and overlaps in Frameworks in the TC to support the development of individual standards (work items) and RSP (an assembly of standards for a specific use)</td>
<td>CAG01</td>
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5.1.4 Improved governance and project management

ISO/TC 215 continues to pursue more rigorous documentation, justification and assessment of proposals for new work, noting that this aligns with ISO strategic directions and recent changes to the ISO/IEC Directives. Such approaches also support the need for the new assessment roles to be performed by the Coordination Group (CAG 2) and x-SDO Coordination Group (CAG 3).

The TG supported the concept of the “bundle” approach, but agreed the need for an understanding of the scope, aim and process, together with worked examples. As bundle work is typically across WGs, they should be managed across work groups.

The pre-new work item assessment of TC215 work items by CAG02 needs to be reviewed. It is proposed that CAG01 explores the possibility of developing a balanced scorecard for the group.

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<tbody>
<tr>
<td></td>
<td><strong>Improved governance and project management</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13.11</td>
<td>Document (initial) new project assessment criteria and processes</td>
<td>CG, EC, AHG-BP Sec</td>
<td>?</td>
</tr>
<tr>
<td>13.13</td>
<td>Update TC 215 guidelines to reflect new processes</td>
<td>Sec, AHG-BP</td>
<td>?</td>
</tr>
<tr>
<td>16.09</td>
<td>Establish first bundles</td>
<td>CAG02</td>
<td>May 2016</td>
</tr>
<tr>
<td>16.10</td>
<td>Aim to complete first bundled standard</td>
<td>WG2</td>
<td>May 2018</td>
</tr>
<tr>
<td>16.11</td>
<td>Develop CSFs for bundles</td>
<td>CAG01</td>
<td>May 2017</td>
</tr>
<tr>
<td>16.12</td>
<td>Explore development of balanced scorecard for TC215</td>
<td>CAG01</td>
<td>May 2018</td>
</tr>
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</table>

5.1.5 Engagement with eHealth stakeholder communities

Continued engagement with key stakeholder communities across the globe is an essential element in ensuring that the work of ISO/TC 215 continues to be relevant, practical, usable and customer-focussed. Such engagement is
also important to ensure that ISO/TC 215 continues to be recognised as an authoritative source of core standards needed for effective deployment of practical eHealth solutions in a world where eHealth is becoming increasingly important. It also helps to secure competent, experienced personnel to work on relevant projects. The Task Group considered three topics on involvement with stakeholders:

**National Member Bodies:** The TG agreed there should be efforts to engage further with Member Bodies, but it was noted that a similar recent exercise was largely unsuccessful. It would be good to aim for increased participation by low and middle income countries and specific on focused development, adoption and use of standards directly applicable to such nations.

**Liaisons and Relationships:** The TG felt that there needed to be a review of liaisons and the TC215 Secretariat has undertaken a review to be completed in late 2016 / early 2017. The Task Group considered a draft role description for a liaison officer.

**Wider stakeholder engagement:** The Task Group felt there needed to be greater external engagement, in terms of interaction with other (e)health related TCs. Vendor participation at TC215 should be a strategic priority and increased impact and applicability of TC215 standards to the vendors of digital health solutions should be achieved.

The Task Group felt it would be helpful to develop success factors for engagement: two such might be ability to meet market need and leveraging existing materials. There needs to be a strategy for marketing and education of the TC’s products and through an educational plan to train professionals, promote the products or even distribute content to countries in need and cannot afford.

Two proposals have been made; to focus engagement on how stakeholder communities can be engaged in the work on implementing standards, and reference to the examples of CHIEF in Canada and CHIME in the U.S. illustrate where “for profit” organizations pay a fee to play which allows them to get their ideas on the table and access the other key players and stakeholders to better understand their needs and stimulate innovative thinking as to how to meet those needs.

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<tbody>
<tr>
<td>13.16</td>
<td>Establish &amp; maintain contact list</td>
<td>Sec</td>
<td>?</td>
</tr>
<tr>
<td>13.17</td>
<td>Develop a stakeholder engagement and education strategy</td>
<td>EC, Sec, AHG</td>
<td>?</td>
</tr>
<tr>
<td>13.18</td>
<td>Establish processes to monitor, review and report on global access, use and support of health informatics standards</td>
<td>EC, Sec, AHG (tbd), JIC/xSDO</td>
<td>?</td>
</tr>
<tr>
<td>16.13</td>
<td>Engage balloting National Member Bodies with a view to stimulating participation and encouraging uptake</td>
<td>CAG01</td>
<td></td>
</tr>
<tr>
<td>16.14</td>
<td>Review all liaisons</td>
<td>Sec</td>
<td></td>
</tr>
<tr>
<td>16.15</td>
<td>Develop CSFs for liaison work</td>
<td>Sec</td>
<td></td>
</tr>
<tr>
<td>16.16</td>
<td>Define the liaison process with other SDOs for specific work items</td>
<td>Sec</td>
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### 5.1.6 Cross SDO collaboration on eHealth standardization

Collaboration with other SDOs working on health informatics standards and avoiding parallel and overlapping work where possible are high priorities for ISO/TC 215 and are reflected in its support for the JIC. The JIC member liaisons are important as the parties share a healthcare focus, but each has its own sphere of standards development.

The Task Group noted that there were two classes of liaison: the formal and active illustrated perhaps by CDISC, and the inactive who perhaps were “friends of friends” or had a legacy of engagement. A segmentation exercise should be undertaken similar to that carried out for prioritising stakeholders.

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</table>
5.2 Identified strategies to achieve the ISO/TC's defined objectives

In addition to specific actions identified in section 5.1, the following are among other strategies being pursued by ISO/TC 215 at a more general level to achieve its objectives, including improvement of its processes.

- Strongly encouraging ISO adoption, re-publication and application of relevant existing standards from other SDOs, where these standards are already established and/or a good fit for business needs;
- Placing greater emphasis on producing a significant set of deliverables from preliminary work item stage to provide a more comprehensive initial draft and better project proposal;
- Giving added priority to standards which do not conflict with other identified standards work but, rather plug any gaps in the available standards coverage;
- Investigating and where possible making greater use of new ways of working electronically using web-based services to extend TC 215 reach and reducing the cost of participation;
- ISO/TC 215 has already sought ISO/CS approval to make greater use of fast track and other approaches for ISO publication of appropriate material produced and maintained by SDOs with which TC 215 collaborates.
6. FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE ISO/TC WORK PROGRAMME

Factors that could affect progression and completion of the work program or acceptance, implementation and use of ISO/TC 215 standards include:

- Lack of stakeholder support;
- Project teams lacking the specific breadth and depth of expertise, understanding and application knowledge;
- Lack of Funding for the Technical Committee and Working Group secretariats;
- Finding two national member bodies prepared to host TC 215 face-to-face meetings each year;
- Failure of collaboration with other SDOs;
- The perception among some that the ISO business model, processes and requirements inhibits ISO/TC 215's ability to work collaboratively on joint publications;
- Securing various collaborative agreements needed for ISO/TC 215 to work collaboratively with other SDOs as an ultimate publisher of key eHealth standards;
- Growing the community of experts and remaining relevant in an area of rapid change;
- Lack of widely applicable processes and information to promote consistency of implementation and validation for eHealth interoperability standards across different domains and realms;
- Health information policies of some health delivery organizations which focus on their immediate needs, limiting their interest in understanding, adopting or participating in standards;
- The need for wider availability, broader uptake, more consistent implementation and continual promotion of appropriate eHealth standards in order to achieve benefits;
- Clarity over validity for each standard including confirmation that the standard will not change or develop within a specified timeframe;
- Potentially increased competition from emerging niche organizations that are entrepreneurial and facilitate standards development in emerging areas as a business opportunity;
- The failure to attract a following, uptake or participation among LMICs and even some developed economies that are attracted to freely available alternatives to ISO/TC 215 standards and cannot justify the costs of participation in its activities.
7. STRUCTURE, CURRENT PROJECTS AND PUBLICATIONS OF THE ISO/TC

7.1 Information on ISO online

This section gives an overview of the ISO/TC’s structure. Further information on TC215 may be found at: https://www.iso.org/committee/54960.html

7.2 Structure of the ISO committee

ISO/TC 215 reviewed its organizational structure and resolved to reduce the number of working groups. The recommended structure, which is being implemented at the same time as this business plan, and its component parts are as depicted in Figure 2.

![Figure 2 - Revised ISO/TC 215 structure (implemented in 2013-2014)](image)

Under this structure, ISO/TC 215 has four on-going working groups with the following scopes:

- **WG 1 Architecture, Frameworks and Models**
  Scope: Standardization of frameworks, architectures, and their components in support of health and healthcare, including standardization of conceptual, logical, and functional requirements, process models and information models.

- **WG 2: Systems and Device Interoperability**
  Scope: Standardization of electronic exchange of information among health and healthcare systems, including information exchange within and among organizations and interoperability of devices.

- **WG 3 Semantic Content**
  Scope: Standardization of methods for the representation and use of concepts, data and knowledge in support of health and healthcare, including standardization of:
  - formal models for the representation and description of concepts;
  - principles for the representation of concepts within terminological resources;
  - principles for the governance and maintenance of terminological resources;
  - methods for the representation and management of knowledge; and
methods for using terminological resources and knowledge in health and healthcare systems and in electronic health records,

but excluding the development and maintenance of actual content of standardized terminological resources, such as those maintained by IHTSDO (SNOMED CT®), WHO (ICD), Regenstrief Institute (LOINC, UCUM) or WONCA (ICPC-2).

- **WG 4 Security, Safety and Privacy**
  
  Scope: Standardization of methods and systems to protect and enhance the confidentiality, integrity and availability of health information, to prevent information systems from adversely affecting patient safety, to protect the privacy of personal information used in health and healthcare, and to ensure the accountability of users of health information systems.

  The intent is that these four "cross-cutting" working groups undertake projects in topic areas that span across various health domains. Experience has shown that there are long-standing overlaps of interest and expertise between the areas addressed by these four primary working groups and that this is likely to continue so that some projects will be progressed as joint work items with experts from multiple working groups.

  Other WGs may be formed from time to time to address specific project needs in particular domains. Currently there is one domain-specific working group as follows:

- **WG 6 Pharmacy and Medicines Business**
  
  Scope: Standardization related to the application of information and communication technology in the domain of pharmacy and medication, including standardization to improve patient safety and the efficiency and interoperability of information systems used in researching, developing, regulating, supplying, using and monitoring pharmaceutical products.

  ISO/TC 215 also has two joint working groups hosted by other technical committees that operate as domain working groups from ISO/TC 215’s perspective.

- **IEC/62A/JWG 7 Safe, effective and secure health software and health IT systems, including those incorporating medical devices**

  Scope: *Standardization in the area of health informatics and electrical equipment in healthcare where ISO/TC 215 and IEC/SC 62A have identified a need for joint standards development.*

  This is a joint working group with IEC/SC 62A Common aspects of electrical equipment used in medical practice.

  JWG 7 and TC215 are currently working on joint standards for the safety of health software and IT systems that incorporate health software or medical devices. This includes projects that span the technology lifecycle, from design and development to implementation and use, addressing both technology developers and healthcare providers. Within TC 215, JWG 7 coordinates closely with WG 2 and WG 4 to ensure consistency with closely related subject matter.

  At the time of this document, there is a proposal open for comment from JWG7 to update the JWG7 title to better reflect market evolution and stakeholder needs. In the 10 years since the creation of the JWG 7. In the past decade, the industry has seen a significant evolution in the information technologies that are being used to provide healthcare, often blurring the lines between medical device technology and health information technology, including health software. JWG7 is seeking comment and confirmation on a revised title that will clearly and accurately indicate to the public at large the important role the JWG plays in carrying out the work programs of IEC/SC 62A and ISO/TC 215. The results of this comment will be included in the final version of this document.

- **ISO/TC 249/JWG 1 Informatics of TCM**

  Scope: *Standardization in the field of medical systems derived from ancient Chinese medicine which shall be able to share one common set of standards. Both traditional and modern aspects of these systems are*
covered. The committee focuses on quality and safety of raw materials, manufactured products and medical devices and of informatics, including service standards limited to involving the safe use and delivery of devices & medicine, but not into the clinical practice or application of those products.

This is a joint working group with and hosted by ISO/TC 249 Traditional Chinese Medicine (TCM).

To assist ISO/TC 215 prioritise its activities and coordinate its work program, progress its strategic and business planning functions and support collaboration with other SDOs operating internationally within the health informatics field, particularly through the JIC, it has established three committee advisory groups (CAGs) with the following scopes.

- **CAG 1 Executive Council (EC)**
  Scope: To provide strategic and business leadership to the Committee.
  Formally, the Executive Council is an advisory group to the Committee Chair. The following objectives are within scope for the Executive Council:
  (a) prioritizing the development of health informatics standards;
  (b) providing access and support for emerging and developing countries; and
  (c) planning, managing, evaluating the work of the committee.

- **CAG 2 Co-ordinating Group (CG)**
  Scope: To prioritise new work item proposals (NPs) with the goal of harmonizing work within TC215 with the following objectives:
  (a) co-ordination of the development of health informatics standards;
  (b) harmonisation of existing and emerging health informatics standards to establish a global framework of consistent and common standards for health systems and health data (together with CAG3); and
  (c) development and maintenance of operational plans and the overseeing of their delivery; addressing TC logistics and expediting the standards development process.

- **CAG 3 Cross-SDO Co-ordination**
  Scope: To plan, determine processes, coordinate and make recommendations to the Joint Initiative Council (JIC) on:
  (a) resolving gaps, overlaps and issues of counterproductive standardization;
  (b) harmonizing existing and emerging health informatics standards; and
  (c) achieving a global framework of consistent and common standards for health systems and health data (together with CAG2).

Note 1: CAG 3 also acts as the externally-focussed coordination group, operating in collaboration with the TC 215/CAG 2 Coordination Group (which is internally focused).

Note 2: CAG3 provides the "Joint Working Group" in the Joint Initiative Charter signed by all Joint Initiative SDOs, which was previously identified as Joint Working Group 9 (JWG 9).

In addition, ISO/TC 215 may constitute Ad-hoc Groups from time to time each for a specific purpose.

Within ISO/TC 215 (the committee), the P-Members, which meet in plenary at the face-to-face meetings of the committee, are the ultimate decision-making body in relation to managing the affairs of the committee within the ISO rules for technical committees. Matters that are administrative will be addressed through an administrative group convened when required by the ISO/TC 215 Secretariat and comprising the secretariats and conveners of working groups, with others by invitation of the Secretariat.

### 7.3 Current projects of the ISO technical committee and its subcommittees

As at July 2016, ISO/TC 215 had 48 approved projects underway:

[https://www.iso.org/committee/54960/x/catalogue/p/0/u/1/w/0/d/0](https://www.iso.org/committee/54960/x/catalogue/p/0/u/1/w/0/d/0)
7.4 Publications of ISO/TC 215

As at July 2016, ISO/TC 215 had produced 169 publications:

https://www.iso.org/committee/54960/x/catalogue/p/1/u/0/w/0/d/0

REFERENCE INFORMATION

Glossary of terms and abbreviations used in ISO/TC Business Plans

General information on the principles of ISO’s technical work

Other references


Annex A: Benefits Flowing from TC 215 Standards

This annex provides examples where ISO/TC 215 standards provide benefits in the delivery of health services, to the broader health system and to the community at large. Applications such as shared EHR and personal health record (PHR) systems rely on eHealth standards in capturing, communicating, collecting, interpreting and presenting information in ways that enable its wider use in the delivery of individual care. Such information typically includes laboratory and diagnostic results, medications, clinical observations, clinical orders, care plans, continuity of care documents, information entered by subjects of care themselves, and financial transactions associated with the provision of care. Examples include:

- ISO 13606 5-part series: Health informatics – Electronic health record communication Developed under Vienna Agreement jointly with CEN/TC251. Parts originally published between 2008-2010 are currently under update to be published targeting 2017
  - 13606-1 Health informatics–EHR Communication Part 1 Reference Model
  - 13606-2 Health informatics–EHR Communication Part 2 Archetype Specification
  - 13606-3 Health informatics–EHR Communication Part 3, Reference Archetypes and Term Lists
  - 13606-4 Health informatics–EHR Communication Part 4, Security
  - 13606-5 Health informatics–EHR Communication Part 5, Interface Specification

- ISO/HL7 27931:2009 Health informatics – HL7 Version 2.5 application protocol for electronic data exchange in healthcare environments


- ISO 12052:2006 Health informatics – Digital imaging and communication in medicine (DICOM) including workflow and data management (due for systematic review update in 2017)


Standards that define how information is structured and content is represented (e.g. via clinical terminologies) seek to ensure that the meaning of health information can be preserved across applications, that it can be used for secondary purposes (with appropriate consents) and that it can be safely and reliably used to support various automated clinical decision support (CDS) applications. Examples include:

- ISO 13119:2012 Health informatics Clinical knowledge resources - Metadata

- ISO/DIS 13120:2013 Health informatics – A syntax to represent the content of classification systems in healthcare

- ISO 21090:2011 Health informatics – Harmonized data types for information interchange

- ISO 1828:2012 Health informatics – Categorial structure for terminological systems of surgical procedures


- ISO TS 16277-1:2015 Health informatics – Categorial structures of clinical findings in traditional medicine – part 1 traditional east Asian medicine

Other eHealth standards focus on interoperability between various devices and information systems and the use of eHealth to support the remote delivery of clinical services, notably:

- ISO/IEEE 11073 series of health device communication standards


Policy development, regulation, monitoring and enforcement within the health system and clinical research depend on health informatics standards to support collection of statistics and comparative measures and biosurveillance systems, research data collections, clinical trials and associated regulatory processes:

- ISO/TR 12773:2009 Health informatics – Business requirements for health summary records
• ISO 21667:2010 Health informatics—Health indicators conceptual framework

Other ways in which ISO/TC 215 standards contribute include the provision of:

• structured frameworks, models and architectures to aid the formal identification of requirements related to health information and workflow, and the development of harmonised eHealth standards and profiles supporting interoperability of systems and preserving the meaning of shared health information, for example:
  - ISO/DIS 13940:2015 Health informatics—System of concepts to support continuity of care
  - ISO TR 14639-1 Health informatics—Capacity-based eHealth architecture roadmap—Part 1: Overview of national e-health initiatives
  - ISO TR 14639-2 Health informatics—Capacity-based eHealth architecture roadmap—Part 2: Architectural components and maturity model
  - ISO 18308:2011 Health informatics

• reports, specifications, standards and guidelines to manage risks arising from the growing application of eHealth in the delivery of health services, to ensure information security, to improve clinical quality and outcomes and to protect the safety and privacy of subjects of care. Examples include:
  - ISO 27799 Health informatics—Information security management in health using ISO/IEC 27002
  - ISO/DIS 22857 Health informatics—Guidelines on data protection to facilitate trans-border flows of personal health data
  - ISO TR17791 Health informatics—Guidance on standards enabling safety in health software
  - ISO 27789 Health informatics—Audit trails for electronic health records
  - ISO/TR 25237:2008 Health informatics — Pseudonymization

• specifications of functional requirements that health information systems should support – to assist in the development, improvement, and acquisition of health information systems and their assessment and certification for regulatory purposes, for example:
  - ISO/HL7 10781:2009 Health informatics—Electronic Health Record—System Functional Model, Release 1.1
  - ISO/HL7 DIS 16527 Health informatics—Personal Health Record System Functional Model, Release 1 (PHRS FM)
  - ISO/HL7 27951:2009 Health informatics — Common terminology services, release 1

• guidance and specifications on the way in which ICT architectural principles, methodologies, processes, technologies, tools and standards should be adopted and applied within the health sector, for example:
  - ISO 12967 series: Health informatics - Service architecture
  - ISO 17115 Health informatics - Vocabulary of terminological systems
  - ISO 10159:2011 Health informatics - Messages and communication - Web access reference manifest
  - ISO/TR 11636:2009 Health informatics – Dynamic on-demand virtual private network for health information infrastructure

• approaches for classification of eHealth standards, identification of gaps and overlaps, collaboration between health informatics SDOs and potentially aiding longer-term consistency and harmonisation of eHealth standards, for example:
  - ISO/TR 13054:2012 Health informatics—Knowledge management of health information standards
  - ISO/TR 16277-1 Health informatics—Categorial structures of clinical findings in traditional medicine - part 1 traditional east Asian medicine
  - ISO/TR 12309:2009 Health informatics – Guidelines for terminology development organizations

• guidance, specifications and profiles to assist in the correct application of eHealth standards to ensure interoperability and safety of systems and information in particular contexts, for example:
  - ISO/DTR 12300 Health informatics—Principles of mapping between terminological resources
  - ISO 14199 Health informatics—BRIDG Model (for clinical research)
Annex B: Assessment of Progress of 2013 Actions

The following tables summarise the specific objectives identified in the main body of this report, the high-level objectives to which they relate and the party currently responsible.

<table>
<thead>
<tr>
<th>ISO/TC 215 work program</th>
<th>Responsibility</th>
<th>Achieved</th>
</tr>
</thead>
<tbody>
<tr>
<td>01: Progression of non-IEEE standards work</td>
<td>WGs, DWGs, JWG</td>
<td>Y</td>
</tr>
<tr>
<td>02: Progression of IEEE fast-track standards work</td>
<td>WG2</td>
<td>Y</td>
</tr>
<tr>
<td>03: Establishing system to anticipate and plan for systematic and/or periodic review</td>
<td>CG</td>
<td>Y</td>
</tr>
<tr>
<td>04: Investigating improvements to systematic and/or periodic review to ensure standards relevant and fit for purpose</td>
<td>EC + TF(tbd)</td>
<td>Not complete</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Structure and scope of ISO/TC 215</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>05: Seek TMB approval for updated ISO/TC 215 scope</td>
<td>GA, Sec, AHG-BP</td>
<td>Y</td>
</tr>
<tr>
<td>06: Complete implementation of organization review including group scopes and transfer of database records</td>
<td>GA, Sec, AHG-BP</td>
<td>Y</td>
</tr>
<tr>
<td>07: Establish plans to resolve JWG 7 scope, title &amp; role</td>
<td>EC, GA, Sec, Oth(tbd)</td>
<td>Y</td>
</tr>
<tr>
<td>08: Establish plans to resolve JWG TCM scope, title &amp; role</td>
<td>EC, GA, Sec, Oth(tbd)</td>
<td>Y</td>
</tr>
<tr>
<td>09: Finalise, approve, circulate and submit updated v3 of TC 215 business plan (BP)</td>
<td>EC, GA, AHG-BP Sec, NMBs</td>
<td>Y</td>
</tr>
<tr>
<td>10: Complete next update of TC 215 BP within 2 years</td>
<td>EC, GA, Sec, AHG</td>
<td>In process 2016</td>
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<thead>
<tr>
<th>Improved governance and project management</th>
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<tbody>
<tr>
<td>11: Document (initial) new project assessment criteria and processes</td>
<td>CG, EC, AHG-BP Sec</td>
<td>To commence in CAG01, CAG02 2016/2017</td>
</tr>
<tr>
<td>12: Establish and elect the CAG 2 Coordination Group (CG)</td>
<td>EC, GA, Sec, AHG-BP</td>
<td>Y</td>
</tr>
<tr>
<td>13: Update TC 215 guidelines to reflect new processes</td>
<td>Sec, AHG-BP</td>
<td>Not complete</td>
</tr>
<tr>
<td>14: Plan pathway for identification of architectural framework and coherent view of eHealth standardization</td>
<td>EC, CG, CAG3, JIC, WG1, AG (tbd)</td>
<td>Not complete</td>
</tr>
<tr>
<td>15: Plan to work with JIC members on analysis of areas requiring standards support to identify gaps in information about standards solutions and gaps in standards coverage</td>
<td>CG, JIC, CAG3, AG (tbd)</td>
<td>TC215 collaborating w/other JIC members on standards set creation initiative</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Engagement with eHealth stakeholder communities</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>16: Establish &amp; maintain contact list</td>
<td>Sec</td>
<td>Complete, available upon request from TC215 Secretariat</td>
</tr>
<tr>
<td>17: Develop a stakeholder engagement strategy</td>
<td>EC, Sec, AHG (tbd), JIC/Xsdo</td>
<td>Not complete</td>
</tr>
<tr>
<td>18: Establish processes to monitor, review and report on global access, use and support of health informatics standards</td>
<td>EC, Sec, AHG (tbd), JIC/xSDO</td>
<td>Not complete</td>
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<tr>
<th>Cross SDO collaboration on eHealth standardization</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>19: Continue support for JIC secretariat</td>
<td>EC, Sec, JIC/xSDO</td>
<td>JIC secretariat currently held by IHTSDO</td>
</tr>
<tr>
<td>20: Seek ongoing maintenance of agreements between ISO and other key SDOs that collaborate with ISO/TC 215.</td>
<td>EC, GA, Sec</td>
<td>In discussion with ISO/CS and ANSI 2016-2017</td>
</tr>
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<table>
<thead>
<tr>
<th>Ref.</th>
<th>Action</th>
<th>Resp.</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.04</td>
<td>Investigating improvements to systematic and/or periodic review to ensure standards relevant and fit for purpose</td>
<td>EC + TF(tbd)</td>
<td></td>
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<tr>
<td>16.01</td>
<td>Develop a method of assessment (quantitative and qualitative) of usability of WG’s products and its implementation</td>
<td>CAG01</td>
<td></td>
</tr>
<tr>
<td>13:10</td>
<td>Complete next update of TC 215 Business Plan within 2 years</td>
<td>CAG01</td>
<td>?</td>
</tr>
<tr>
<td>16.02</td>
<td>Discuss revised statement of scope with TMB and other relevant committees</td>
<td>EC</td>
<td></td>
</tr>
<tr>
<td>16.03</td>
<td>WG3 to share framework document with CAG01</td>
<td>WG3</td>
<td></td>
</tr>
<tr>
<td>16.04</td>
<td>Each WG to consider applicability of WG3 framework</td>
<td>CAG01</td>
<td></td>
</tr>
<tr>
<td>16.05</td>
<td>Finalize the decision and process for a potential split of TMTF from WG3</td>
<td>CAG01</td>
<td></td>
</tr>
<tr>
<td>16.06</td>
<td>Finalize WG3 Framework approach to guide the development of semantic content standards</td>
<td>WG3</td>
<td></td>
</tr>
<tr>
<td>16.07</td>
<td>Set up a regular review of the WG3 Framework and work program based upon the assessment of utility of items and national priorities for new work</td>
<td>WG3</td>
<td></td>
</tr>
<tr>
<td>16.08</td>
<td>Identify gaps and overlaps in Frameworks in the TC to support the development of individual standards (work items) and RSP (an assembly of standards for a specific use)</td>
<td>CAG02</td>
<td></td>
</tr>
<tr>
<td>13.11</td>
<td>Document (initial) new project assessment criteria and processes</td>
<td>CAG01, Sec</td>
<td>?</td>
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<tr>
<td>13.13</td>
<td>Update TC 215 guidelines to reflect new processes</td>
<td>Sec</td>
<td>?</td>
</tr>
<tr>
<td>16.09</td>
<td>Establish first bundles (NWIP ballot launched, closes Sep 2016, results to be reviewed in Lillehammer, Nov 2016)</td>
<td>CAG02</td>
<td>May 2016</td>
</tr>
<tr>
<td>16.10</td>
<td>Aim to complete first bundled standard</td>
<td>WG2</td>
<td>May 2018</td>
</tr>
<tr>
<td>16.11</td>
<td>Develop CSFs for bundles</td>
<td>CAG01</td>
<td>May 2017</td>
</tr>
<tr>
<td>16.12</td>
<td>Explore development of balanced scorecard for TC215</td>
<td>CAG01</td>
<td>May 2018</td>
</tr>
<tr>
<td>13.16</td>
<td>Establish &amp; maintain contact list</td>
<td>Sec</td>
<td>?</td>
</tr>
<tr>
<td>13.17</td>
<td>Develop a stakeholder engagement strategy</td>
<td>CAG01, JIC</td>
<td>?</td>
</tr>
<tr>
<td>13.18</td>
<td>Establish processes to monitor, review and report on global access, use and support of health informatics standards</td>
<td>CAG01</td>
<td>?</td>
</tr>
<tr>
<td>16.13</td>
<td>Engage ballotting National Member Bodies</td>
<td>Sec</td>
<td></td>
</tr>
<tr>
<td>16.14</td>
<td>Review all liaisons – already underway</td>
<td>Sec</td>
<td>Early 2017</td>
</tr>
<tr>
<td>16.15</td>
<td>Develop Critical Success Factors for liaison work</td>
<td>Sec</td>
<td></td>
</tr>
<tr>
<td>16.16</td>
<td>Define the liaison process with other SDOs for specific work items</td>
<td>Sec</td>
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<td></td>
<td>Cross SDO collaboration on eHealth standardization</td>
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<tr>
<td>13.20</td>
<td>Seek ongoing maintenance of agreements between ISO and other key SDOs that collaborate with ISO/TC215</td>
<td>EC, GA, Sec</td>
<td>?</td>
</tr>
<tr>
<td>13.15</td>
<td>Work with JIC members on analysis of areas requiring standards support to identify gaps in information about standards solutions and gaps in standards coverage</td>
<td>JIC, CAG03</td>
<td>?</td>
</tr>
<tr>
<td>16.17</td>
<td>Develop list of success factors for SDO working</td>
<td>CAG03</td>
<td></td>
</tr>
<tr>
<td>16.18</td>
<td>Establish collaboration on semantic content standards</td>
<td>WG3</td>
<td></td>
</tr>
<tr>
<td>16.19</td>
<td>Undertake strategic review of HL7 relationship (currently underway within ANSI / ISO/CS via TMB Task Force)</td>
<td>CAG01</td>
<td>In progress</td>
</tr>
</tbody>
</table>

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**Cross SDO collaboration on eHealth standardization**

- **13.20** Seek ongoing maintenance of agreements between ISO and other key SDOs that collaborate with ISO/TC215
  - **Resp.** EC, GA, Sec
  - **Date** ?

- **13.15** Work with JIC members on analysis of areas requiring standards support to identify gaps in information about standards solutions and gaps in standards coverage
  - **Resp.** JIC, CAG03
  - **Date** ?

- **16.17** Develop list of success factors for SDO working
  - **Resp.** CAG03

- **16.18** Establish collaboration on semantic content standards
  - **Resp.** WG3

- **16.19** Undertake strategic review of HL7 relationship (currently underway within ANSI / ISO/CS via TMB Task Force)
  - **Resp.** CAG01
  - **Date** In progress