ISO/TC 215, *HEALTH INFORMATICS*

Clause 2.1.2 of the ISO/IEC Directives, Part 1

ISO/TC 215 Chair

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Message from the Chair

The health informatics landscape is undergoing rapid transformation driven by technological innovation, shifting population needs, and evolving health-system priorities. These advances are reshaping how health information is generated, shared, and used, presenting both new opportunities and challenges. Understanding these forces is essential to ensuring that ISO/TC 215 standards remain relevant, responsive, and globally harmonized.

What is the main market trend?

Intelligent technologies are being rapidly advanced into all aspects of health and healthcare, from generative AI to health agents to AI/ML-enabled apps & devices, promising revolutionary benefits, yet challenging traditional aspects such as interoperability, safety, effectiveness and security.

Why are standards important?

Standards developed by ISO/TC 215 – Health informatics bring multiple, cascading benefits across the healthcare ecosystem including:

1. Safe, effective, patient-centered care,
2. Improved decision-making & clinical quality,
3. Efficiency, cost reduction and productivity gains,
4. Support for population health, research & analytics, and
5. Person-centered empowerment

Who participates in standards development in this topic?

ISO/TC 215 encompasses a diverse and globally distributed stakeholder community spanning public health authorities, national standards bodies, academia, industry, and clinical organizations. Its ecosystem bridges the health, ICT, and life-sciences sectors, ensuring that standards reflect both technological innovation and health-system priorities.

What are the committee's strategic priorities?

Strategic focus areas for 2026-2028 include:

1. Data & Knowledge Sharing
2. Artificial Intelligence
3. Cybersecurity
4. Healthcare Innovation
5. Operational Excellence

How can you get involved?

Reach out to the ISO member in your country to learn more about participating in ISO/TC 215.

ISO/TC 215 standards support the following SDGs

iso.org/sdg

Introduction

The evolution of formal strategic planning in ISO Technical Committees is a key measure in supporting the ISO Strategy 2030 vision of making lives easier, safer and better. This document is designed to aid committees and their stakeholders in:

- Identifying benefits and vision of standardization within the committee's field of activity
- Linking benefits to higher strategic imperatives (ISO Strategy 2030, UN SDGs, London Declaration Action Plan)
- Prioritizing among projects and allocating resources
- Providing transparency and communicating through a format adapted to three key audiences (general public, TMB and other TCs, and internal TC stakeholders)
- Supporting data-driven continuous improvement, including user perspectives where available
- Maintaining strategic flexibility for different market cadences

International standards embody the essential principles of global openness and transparency, consensus and technical coherence. These are safeguarded through its development in ISO Technical committees, representative of all interested parties, supported by a WTO TBT-compliant public enquiry phase.

International standards are developed through a member-driven market-centric process, where any P-member may submit a proposal for new work.

This document represents an important filter through which new work items should be considered by P-members of a committee and shall be referenced in new work item proposals submitted to the committee per clause 2.3.4 of the ISO/IEC Directives, Part 1.

Beginning in 2026, deviations from this strategy shall be rationalized in new work item proposals.

Meeting global needs

To realize our vision, we must develop consensus-based standards that are relevant and respond to current and future challenges. We must focus on getting the right standards to market at the right time, and with the right content and in the right format.

Business environment and future trends

The health informatics landscape is undergoing rapid transformation driven by technological innovation, shifting population needs, and evolving health-system priorities. These advances are reshaping how health information is generated, shared, and used, presenting both new opportunities and challenges. Understanding these forces is essential to ensure that ISO/TC 215 standards remain relevant, responsive, and globally harmonized.

- **Artificial Intelligence (AI)** is rapidly being adopted in healthcare applications, driving efficiency, improving diagnostic accuracy, and strengthening health-system resilience. These shifts are transforming care delivery models, changing market dynamics and challenging existing regulatory frameworks. Agentic platforms and conversational health agents are increasingly being deployed to optimize patient care and engagement. However, divergent national and regional approaches to AI governance may create trade barriers and interoperability challenges. Additionally, understanding and managing the safe, effective and ethical use of these technologies, while safeguarding privacy, security, and accountability is a key global concern.
- **Cybersecurity & Privacy** remain persistent global challenges in health informatics. As health data becomes increasingly digital, distributed, and interconnected, the potential impact of security breaches grows. The healthcare sector faces rising threats from theft and misuse of personal identity and clinical data for financial or political purposes, to large-scale ransomware attacks that can disable entire health systems. The emergence of quantum computing raises new risks to existing encryption and authentication methods, demanding forward-looking standards for data protection and resilience. Ensuring confidentiality, integrity, and availability of health information is fundamental to sustaining trust in digital health systems and safe cross-border data exchange.
- **Data & Knowledge Sharing** have become central to modern healthcare and research. Advances in computational capacity, data analytics, and communications technologies now enable the capture and exchange of high-fidelity, high-frequency data across diverse and distributed systems. The ability to transform this data into actionable knowledge supports clinical decision-making, continuous learning, and precision medicine. Building life-long health information archives is now in reach, improving care continuity and empowering individuals to manage their own health. Achieving these benefits requires interoperability across information systems and geographies, as well as technology-independent persistence, to ensure information remains usable as platforms evolve. Effective standards for data structure, semantics, provenance, and governance are essential to

unlock these capabilities and to enable trusted data sharing for population health analytics and life-sciences research.

- **Person-centric health, wellness and healthcare** are increasing priorities as health systems aim to empower individuals and their families to manage their own health in coordination with providers. Achieving this requires access to and control of personal health data across settings and over time. Standards that enable secure, interoperable data exchange support shared decision-making, continuity of care, and personalized treatment. The growing use of genomic and other omic data reinforces the need for frameworks that integrate person-level information safely and ethically into clinical and wellness contexts.
- **Telehealth & Virtual Care (TVC)** have expanded rapidly since the early 2020s enabling care delivery at scale for underserved and remote populations, as well as those better managed at home. These models rely on secure, interoperable technologies to ensure data accuracy, continuity of care, and clinical safety across settings. Standardization is essential to support consistent quality, authentication, and integration of telehealth services within broader health information systems.

Technology continues to evolve rapidly, especially in personalized health through wearable sensors, AI-enabled applications and intelligent agents. As these innovations move into mainstream healthcare, interoperability, quality, and safety standards will be required to ensure tools are effectively integrated within the digital health ecosystem and support consistent, reliable care across settings.

Benefits of standards and vision for standardization in the field of activity

Standards developed by ISO/TC 215 – Health informatics bring multiple, cascading benefits across the healthcare ecosystem. These advantages underline the rationale for investing in standardization, and help to explain why consensus-based, timely, relevant standards are critical.

Key benefits of health informatics standardization

Safe, effective, patient-centered care

Standards enable clinicians, caregivers, patients, and service providers to exchange, interpret and use health data meaningfully. Interoperability based on standards supports better coordination of care, reduces treatment errors, and helps ensure continuity across providers.

Improved decision-making & clinical quality

More complete, accurate, meaningful health information allows for better diagnoses, treatment planning and follow-up. Standards reduce ambiguity, help ensure consistent meaning of terms (semantics), and permit data to be reused for monitoring, quality improvement, research, and analytics.

Efficiency, cost reduction and productivity gains

Standards reduce duplication (e.g. repeat tests), minimize manual re-entry, streamline administrative workflows, and lower transaction costs. They contribute to reducing physician and caregiver burden, which supports better staff work life and reduces costs overall.

Innovation enablement and market expansion

Clear, stable, widely accepted standards reduce uncertainty for vendors and developers, encourage compatibility and modularity, and enable entry of new participants (smaller firms, cross-disciplinary services). This helps scale virtual care, AI/ML services, remote monitoring, and other services.

Support for population health, research & analytics

Shared data using common formats and semantics improves the ability to conduct public health surveillance, epidemiology, life-sciences research, real-world evidence studies, precision medicine, and longitudinal health analytics. Standardization increases comparability and aggregation across institutions and countries.

Data security, privacy, and trust

When standards embed robust specifications for confidentiality, access control, auditing, identity, and technical resilience, they help ensure data is exchanged and used safely. This fosters trust among patients, providers, regulators, and other stakeholders.

Person-centered empowerment

Standards help individuals to access, receive, share, and manage their own health data (through portals, apps, and other digital tools), facilitating active participation in their own health journeys, feedback loops, and shared decision-making.

Vision for standardization in health informatics

To make the above benefits real, relevant and timely, our vision is that:

- Health informatics standards will be responsive to emerging technological, regulatory, and societal needs (including AI, telehealth, security, privacy, data sharing, and precision medicine).
- These standards will support interoperability across devices, applications, institutions, jurisdictions and care settings (acute, primary, community, home, virtual, public health, research).
- Standards developed will be based on market need and clearly specify requirements for users and wherever possible avoid need for duplication or divergence from other standardization efforts.

	• We will strive to release relevant standards quickly enough to meet demand, but with sufficient rigor to ensure safety, reliability, clarity, and global acceptance. • We will build capacity and promote adoption: by engaging stakeholders broadly (governments, providers, vendors, patients, regulators, etc.), raising awareness, training, and ensuring that standards are maintained and updated in response to feedback and evolving use. ISO/TC 215 will monitor and measure impact: use cases, deployment evidence, feedback, and outcomes data should inform whether the standards are serving as intended, and guide refinement or discontinuation where appropriate.
 **Reflections on current publications and their market impacts**	ISO/TC 215's portfolio has matured significantly over the past cycle, evolving from foundational informatics concepts to widely implemented interoperability specifications. The suite of **Identification of Medicinal Product (IDMP)** standards opens opportunities for regulatory submission harmonization, adverse event declaration efficiency, medicinal (or substance) shortages, clinical use of regulatory approved data (enabling cross border interoperability), clinical decision support, and more. Adoption of this suite of standards is growing across the world and requires the development of supporting standards such as ontology frameworks. Health information exchange requires an extensive set of standards, both at the conceptual / semantic level as well as at the systems level (e.g., electronic health record systems). ISO/TC 215 has developed a significant set of standards to support this information exchange ranging from **ISO 13940:2015 (Health informatics — System of concepts to support continuity of care)**, with a second edition expected in 2026, and the multi-part series **ISO 13606 (Health informatics — Electronic health record communication),** with a revision underway. Security is at the core of any trusted exchange of health information, but it also needs to be coordinated with foundational non-sector specific security standards. **ISO 27799:2025 (Health informatics — Information security controls in health based on ISO/IEC 27002)** achieves exactly that, leveraging the foundational standard from ISO/IEC JTC 1/SC 27, and providing specific guidance for its application in healthcare contexts. Additionally, ISO/TC 215 works closely with IEC/SC 62A on security-related standards for medical device technology. The **International Patient Summary (ISO 27269)** defines a core dataset for patient summaries supporting unplanned and cross-border care and improving continuity of care. A significant cross-SDO partnership, IPS, has evolved through a multi-organization collaboration, and its principles are referenced in the European Health Data Space, the EU eHealth Network, the WHO Smart Guidelines, and several national digital-health strategies. This harmonized development and adoption illustrates how coordinated international standards efforts enable interoperable health information exchange and strengthen continuity of care worldwide. Standards such as **ISO 13131:2021 (Telehealth services – Quality planning guidelines)** and **ISO/TS 82304-2:2021 (Health and wellness apps – Quality and reliability rating)** have provided essential guidance for strengthening telehealth and digital-health quality systems. These standards are being applied internationally to support the expansion and governance of virtual-care ecosystems following the COVID-19 pandemic. The **ISO/IEC Joint Working Group 3 (JWG 3)** unites experts from **ISO/IEC JTC 1/SC 42 (Artificial Intelligence)** and **ISO/TC 215 (Health Informatics)** to develop standards and guidance for the safe and trustworthy use of AI in health applications. Within **ISO/TC 215/SC 1 (Genomics Informatics)**, collaboration across SDOs remains incredibly important to advance interoperability between clinical and research genomics data, patient healthcare data and ultimately supporting precision-medicine initiatives worldwide. Examples include **ISO 21393:2021 (Genomics informatics — Omics Markup Language (OML)** and **ISO 20428:2024 (Genomics Informatics — Data elements and their metadata for describing structured clinical genomic sequence information in electronic health records)**. Within **ISO/TC 215/SC 2 (Pharmacy and Medicines Business)**, collaboration with the **International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH)** ensures integration of regulatory requirements into ISO standards which address both regulatory and clinical use. Understanding how the scope of the broad landscape of health informatics standards intersects is often challenging, at best. The **ISO 23903:2021 (Health informatics — Interoperability and integration reference architecture — Model and framework)** provides a robust approach for understanding how health informatics standards are interrelated, facilitating improved coordination between specifications, especially when they are developed by different committees, as well as identifying gaps that should be addressed. Collectively, these publications have reinforced **ISO/TC 215's position as the global reference for health-informatics standardization**, shaping the international health-informatics ecosystem and providing the semantic and structural foundation for digital-health transformation worldwide.

Sustainability and climate change

Although sustainability, net-zero, and climate change are not core areas for ISO/TC 215, the committee's work contributes indirectly to these global goals.

Digital health standards enable more efficient, data-driven, and distributed models of care, reducing travel, paper use, and duplication of services. Food and nutrition standards include a means for calculating total material requirement (TMR) facilitating informed consumer decision making. Informatics frameworks for health-facility assessment can incorporate indicators such as carbon footprint, energy efficiency, and lifecycle performance. As digital infrastructure expands, energy efficiency and environmental impact of health information systems and AI models are gaining importance — our collaboration with ISO/IEC JTC 1/SC 42 (Artificial Intelligence) supports the responsible and energy-efficient application of AI in health.

By promoting interoperable, resource-efficient information systems and supporting remote-care solutions, ISO/TC 215 aligns with the ISO Strategy 2030 and the London Declaration, advancing environmentally responsible and resilient digital-health ecosystems.

As a result, although it has been argued that various projects within ISO/TC 215 actually address all 17 of the United Nations Sustainable Development Goals (SDG), six have been identified as particularly falling within the committee's scope of work:

Goal 3	***Target 3.8 (universal health coverage and access to quality healthcare services) and Target 3.d (health risk monitoring and management)*** *– Health informatics standards that advance the utilization of information technology to improve the health & wellness of all individuals around the world are most aligned with this goal.*
Goal 8	***Target 8.2 (higher economic productivity through innovation and technology) and Target 8.3 (formalization and growth of MSMEs)*** – ISO/TC 215 standards that directly improve the health of individuals and communities, directly contribute to economic growth. They also support advancement of health-related professions and services.
Goal 9	***Target 9.1 (development of reliable and resilient infrastructure) and Target 9.b (support for domestic technology development and innovation)*** – Health informatics standards lay the foundation for advancing the state-of-the-art of healthcare technology, enabling new creative solutions, and doing so "at scale" with improved infrastructure.
Goal 10	***Target 10.2 (empowerment and inclusion of all people regardless of status) and Target 10.3 (equal opportunity through elimination of discriminatory practices)*** – Standardized health information technology supports the deployment of care across socioeconomic barriers and even geographies.
Goal 11	***Target 11.3 (inclusive and sustainable urbanization) and Target 11.b (resilient and sustainable community policies)*** – Health and wellness and healthcare are key aspect to any community, and health informatics standards help enable the technology infrastructure that may be deployed at public scale, from homes to clinics to hospitals to entire regions and countries to cross-national support.
Goal 17	***Target 17.6 (multi-stakeholder knowledge-sharing partnerships) and Target 17.9 (capacity building in developing countries)*** – Healthcare represents a substantial portion of the global economy and informatics standardization requires close coordination with many other partners in many other areas. As stated above, some ISO/TC 215 projects have selected all 17 SDG boxes, indicating the cross-goal partnerships that are critical for successful standardization and improving lives.

All voices heard

We need to ensure that we attract and retain the best experts and enable everyone to participate. We must listen to all voices, both in the development of standards and when making decisions as an organization.

Stakeholder mixture and engagement

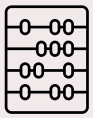
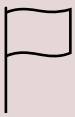
ISO/TC 215 encompasses a diverse and globally distributed stakeholder community spanning public health authorities, national standards bodies, academia, industry, and clinical organizations. Its ecosystem bridges the health, ICT, and life-sciences sectors, ensuring that standards reflect both technological innovation and health-system priorities.

Key collaborators include WHO, CEN/TC 251, HL7 International, SNOMED International, IHE, GS1, IEEE, and many others, with over 50 committees and other organizations in liaison with ISO/TC 215. Additionally, within ISO/TC 215/SC 1 (Genomics Informatics), the Global Alliance for Genomics and Health (GA4GH), and within ISO/TC 215/SC2 (Pharmacy and Medicines Business), the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), and numerous others actively collaborate on shared areas of interest. These partnerships enable alignment between health informatics, genomics, and emerging data standards across disciplines. The committee's stakeholder base also includes patient advocacy groups, professional societies, researchers, and private-sector innovators, supporting balanced consensus across clinical, policy, and technical domains. The success of the International Patient Summary

	(IPS) (ISO 27269) demonstrates the impact of this multi-stakeholder engagement, adopted by numerous national programs and referenced by WHO initiatives. Going forward, ISO/TC 215 will strengthen engagement through capacity-building for low- and middle-income countries, increased collaboration across AI, telehealth, and genomics domains, and targeted communications to improve awareness and adoption of published standards.
 **Developing country perspectives**	ISO/TC 215 actively supports participation from developing and emerging economies to ensure that health informatics standards are globally relevant and practical to implement. Many member countries are building foundational digital-health infrastructure, and access to interoperable, open standards helps accelerate progress while reducing reliance on proprietary systems. Standardized health informatics technologies enable solutions that can be deployed across geographies and scaled across populations, both crucial for developing countries. Through collaboration with the World Health Organization (WHO) and regional partners, ISO/TC 215 contributes to capacity-building initiatives, guidance on implementation, and awareness of digital-health standards. The committee continues to encourage greater representation from low- and middle-income countries (LMICs) in working groups and leadership roles. These efforts align with the ISO Strategy 2030 commitment to inclusivity and equitable global impact, ensuring that international standards support all health systems—regardless of their level of digital maturity.

ISO Standards used everywhere

To encourage the widespread use of ISO standards and attract experts to the development process, we must clearly demonstrate the benefits of using ISO standards.

 **Coordination and cohesion**	ISO/TC 215 maintains extensive coordination with standards bodies, industry consortia, and policy organizations to ensure coherence and interoperability across the global health-informatics landscape. Under the **Vienna Agreement**, ISO/TC 215 collaborates closely with **CEN/TC 251** to develop and maintain joint ISO/EN standards, a partnership that remains vital as Europe advances the **European Health Data Space (EHDS)**. The committee also works with **HL7 International, SNOMED International, Regenstrief Institute (LOINC, UCUM), IHE International, GS1**, and the **World Health Organization (WHO)** to align data models, terminologies, and implementation frameworks. Technical coordination extends across ISO and IEC committees, including **ISO/IEC JTC 1/SC 42 (Artificial intelligence**), **IEC/SC 62A (Medical devices), ISO/IEC JTC 1/SC 27 (Security)**, and **ISO/IEC JTC 1/SC 32 (Data management and interchange)**. Collaboration with **GA4GH** through **ISO/TC 215/SC 1 (Genomics informatics)** ensures interoperability between genomics, clinical and research data, while engagement with **ISO/TC 249 (Traditional medicine)** and the emerging **ISO/IEC JTC 3 (Quantum technologies) and JTC 4 (Smart and sustainable cities and communities)** expands health-informatics application domains. This cohesive network strengthens alignment, reduces duplication, and ensures globally consistent and complementary standards.
 **National adoption perspectives**	ISO/TC 215 works closely with many global organizations to ensure consistent health informatics standards. Under the Vienna Agreement the committee partners with the European standards committee CEN/TC 251, Health informatics, to develop joint ISO/EN standards, crucial for the European Health Data Space. The committee collaborates with HL7 International, SNOMED International, LOINC, IHE International, GS1, and WHO to align terminologies, data models, and implementation frameworks. Technical coordination spans ISO and IEC committees including ISO/IEC JTC 1/SC 42 (AI), IEC/SC 62A (medical devices), ISO/IEC JTC 1/SC 27 (security), and ISO/IEC JTC 1/SC 32 (data management). Collaborations with GA4GH, ISO/TC 249, and ISO/IEC JTC 4 extend health-informatics into genomics, traditional medicine, and smart city applications. Together, these partnerships minimize duplication and ensure globally consistent standards and support ISO/TC 215's role in setting a foundation for consistent, secure, and patient-centered digital-health systems across diverse national contexts.
 **Conformity assessment**	Conformity-assessment competency has been recognized as a key growth area within ISO/TC 215, supporting the quality, credibility, and practical implementation of health-informatics standards. The committee has developed guidance materials to help technical leaders design standards that better support conformity-assessment processes, improving the consistency and readiness of specifications for validation and certification activities. ISO has also provided targeted training for ISO/TC 215 leadership on Management System Standards (MSS) and alignment with ISO/CASCO principles. Building on this foundation, the committee is exploring opportunities to integrate conformity-assessment concepts within emerging domains, including: 1. Artificial Intelligence (in coordination with JTC 1/SC 42)

	2. Information Security Management (in coordination with JTC 1/SC 27) 3. Telehealth & Virtual Care (TVC) 4. Privacy Management of Personal Health Information (PHI) These efforts will enhance the robustness, trustworthiness, and adoption of ISO/TC 215 deliverables across global digital-health ecosystems.

ISO TC 215 Strategic Objectives

NOTE: The following table was created in alignment with a previous version of the ISO SBP template and therefore is not aligned with the most recent layout and content directives. This section will be updated to reflect the latest SBP template in its next revision.

Objectives	Responsible SC or WG (if applicable)	Proposed actions	Priority (HIGH, MEDIUM, LOW)
To advance standards-based *Data & Knowledge Sharing*	TC215	1. Develop standardized components in support of a patient centric, comprehensive, lifetime, cloud-based continuity of care record – a. Continuing with the revision and promoting the use of ISO 13940 ContSys at its interface with the conceptual basis underlying care records and information standards supporting care process b. Updates to ISO 13606 EHRCOM series both for archival format & interoperability, including FHIR compatibility, standard serialisation formats, and maintaining conceptual integrity with ISO 13940 c. Coordinate with liaison organizations to facilitate implementation pathways for the above 2. Coordinate with European members and related liaison organizations to support the European Health Data Space (EHDS) project, European Data Act, and European AI Act 3. Develop standards that facilitate knowledge capture and use 4. Advance quality-focused standardization from the capture and persistence of granular data and knowledge to the processes for its use	HIGH HIGH MED MED
	SC1	1. Develop standards to support genomics as well as multi-omics informatics across national genomics programs, government agencies and industry 2. Focus on standards for secondary use of genomics information for other purposes such as clinical research & clinical care advancement; establish SC1 WG2; ISO/TR 25313:2025 is an SC1 success providing strategic direction. 3. Work closely with other SDOs and liaisons to ensure data can be shared between genomics, clinical research and healthcare (GA4GH, HL7, IEEE BioCompute) 4. Review genomics standards landscape and select identify appropriate standards to test data flow and interoperability toward precision medicine 5. Expand committee liaison relationships to support global coordination priorities, including with the World Health Organization and others.	HIGH HIGH MED MED MED
	SC2	1. Develop standards to support medicinal product master data interoperability	HIGH
To enable the safe and effective use of Intelligent Technologies	TC215	1. Coordinate closely with ISO/IEC JTC 1/SC 42 and other liaison organizations to identify and develop AI-focused standards that meet global needs 2. Extend the ISO/IEC JTC 1/SC 42 AI concepts and terms to include health informatics items 3. Analyse the development of an MSS and conformance that can span the breadth of applications and systems in the health informatics space, leveraging work from ISO/IEC JTC 1/SC 42 4. Analyse the use of AI agents in healthcare, including multi-modal conversational agents, and initiate standardization to facilitate their safe and effective use 5. Develop standards related to AI-focused data quality and information governance	HIGH HIGH MED MED MED

		6. Identify workforce challenges and opportunities resulting from the use of intelligent technologies and develop guidance for areas such as retraining	MED
	SC1	1. Coordinate and align ISO/TC 215/SC1 AI activities with ISO/TC 215 TF5. 2. Work closely with the GA4GH Data Security Work Steam to identify joint standards development projects e.g., “verifiable credentials”.	HIGH HIGH
	SC2	1. Include machine usable elements in the standard developed, to enable for example, ontologies.	HIGH
To ensure cybersecurity standards are current with this rapidly evolving aspect of informatics	TC215	1. Analyse the challenges posed by quantum computing (post quantum cybersecurity) and update or develop standards to meet these new technologies 2. Analyse the challenges and opportunities posed by AI technologies to cybersecurity, including AI/ML-enabled applications, and develop standards as needed 3. Analyse the need and approach for standardization related to zero trust security 4. Coordinate with liaison organizations for cybersecurity, including ISO/IEC JTC 1/SC 27 5. Investigate the requirements for medicinal products resulting from the European NIS2 legation and similar initiatives in other regions	MED HIGH LOW HIGH MED
	SC1	1. Align with ISO/TC215 and related standards organizations to identify existing and needed standards to support the safe and secure exchange of genomics information;	MED
	SC2	N/A	
Healthcare Transformation	TC215	1. Develop a committee-wide standardization strategy for advancing “5P” medicine 2. Identify and develop standards supporting clinical care pathways 3. Publish standards that support personalized health, wellness and healthcare, including personalized health navigation (PHN), and digital therapeutics (DTx) 4. As recommended by TC 215/TF 7, review the TC 215 standards portfolio to determine which standards may require enhancement to better support the technologies, info or infrastructure and processes used in virtual care. 5. Develop an MSS for TVC systems 6. Develop a plan and specifications addressing conformity assessment to IDMP standards 7. Analyse opportunities for the use of ageing, longevity and lifestyle (A2L) research to create standards for individuals and communities, coordinating with liaison organizations such as ISO/TC 314 Ageing societies 8. Establish a working relationship with ISO/IEC JTC 4 for how health informatics may be integrated into smart cities standards	HIGH LOW MED HIGH HIGH MED MED LOW
	SC1	1. Analyse the challenges and opportunities posed by AI technologies to cybersecurity, including AI/ML-enabled applications, and develop Genomics-AI standards as needed 2. Expand liaisons across ISO to ensure coordination and alignment. For example, ISO/IEC JTC 1/SC 42 3. Align with National Precision Medicine Programs such as those across Asia (e.g., Singapore, Japan); secondary use of genomics information is a key component to success 4. Position SC1 as the epicentre for communication between SDOs and major Genomics Programs to achieve interoperability toward realizing precision medicine; cross SDO workshops are critical	HIGH MED HIGH MED
	SC2	1. Publish a standard for medicinal product master data used in clinical practices 2. Identify and develop a standard to support the mobile access to digital information (e.g. patient instructions) 3. Identify and develop a standard to support the minimal file for immunization	HIGH HIGH HIGH

Operational Excellence	TC215	1. Complete publication of the new Strategic Business Plan and integrate its use into committee decision making and other management activities 2. Complete the committee transition to use the OSD platform for all projects 3. Advance key tools from ISO/TC 215/TF 3 Outreach & Communications, including a digital “Standards Catalog” tool, social media presence and article / blog publication, and committee-specific web page for non-standards experts. 4. Complete the transition of ISO/TC 215/WG 6 to ISO/TC 215/SC 2, enabling the committee to better manage its extensive work program 5. Coordinate the reorganization of ISO/TC 249 Traditional medicine and its new subcommittees with the existing liaison and joint work of ISO/TC 215 6. Consider opportunities for reorganizing committee internal groups to achieve better efficiencies and engagement, such as the use of task groups managed by ISO/TC 215 CAG 1 and CAG 2 7. Complete the development of processes, tools and training to Improve the quality and consistency of all PWI & NP proposals 8. Develop an implementation training support for all experts and committee leadership in effectively using ISO processes and tools for all projects 9. Establish approaches for better engagement of and contributions from non-committee experts 10. Identify and establish a process and tool set for integrating HTML-based publications from committee liaison A organizations into ISO publications 11. Establish a task group to periodically evaluate and identify emerging technologies in the area of health informatics and the need for standards development 12. Develop guidance (“handbook”) materials supporting the operationalization of ISO 23903 Interoperability & Integration Reference Architecture 13. Ensure appropriate resources and focus are provided to support key liaison organisations 14. Investigate, assess and implement further internal ISO/TC 215 process and quality improvement initiatives	HIGH HIGH HIGH HIGH MED LOW MED MED LOW MED LOW TBD TBD TBD TBD
	SC 1	1. Operationalize use of the ISO/TC215 Strategic Business Plan and integrate its use into committee decision-making and other management activities 2. Complete the committee transition to use the OSD platform for all projects 3. Train new ISO/SC1 Convenors – WG1, TFs, AHGs 4. Consider growing need for new WGs in the future (e.g., WG2 Secondary Use of Genomics Data, WG3 Data Security)	HIGH MED HIGH MED
	SC 2	1. Develop a training tool for new SC experts	LOW