



Australian Government
Australian Digital Health Agency

National Framework for Digital Health Standards

Connecting Australian Healthcare
National Healthcare Interoperability Plan

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Australian Digital Health Agency

ABN 84 425 496 912; GPO Box 9942 Canberra ACT 2601

Telephone: 1300 901 001; Web: www.digitalhealth.gov.au; Email: help@digitalhealth.gov.au

Acknowledgement of Country

All partners acknowledge and respect Aboriginal and Torres Strait Islander peoples as the Traditional Custodians of Country throughout Australia and their continuing connection to land, seas and community. We pay our respects to their cultures and to Elders past and present.

Thank you to partners and contributors

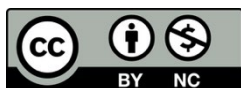
Thank you to the partners, organisations, healthcare providers and Australians from all walks of life who contributed to the strategy and broader consultations. We appreciate all who gave their time, experience and expertise to contribute to Australia's digital health transformation journey.

Role of the Australian Digital Health Agency

The Australian Digital Health Agency (the Agency) is a corporate Commonwealth entity supported by all Australian governments to accelerate adoption and use of digital services and technologies across the Australian health ecosystem, as set out under the Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016 (Agency Rule). The Agency Rule was created under the Public Governance, Performance and Accountability Act 2013. Under the Agency Rule, the Agency is charged with developing a digital health strategy at the national level for Australia.

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1. Executive summary

The National Framework for Digital Health Standards (Standards Framework) sets out a nationally coordinated approach to the adoption and implementation of digital health standards in Australia. Developed by the Australian Digital Health Agency (the Agency), this Standards Framework aims to strengthen interoperability, improve healthcare outcomes, and support the digital transformation of the health system.

Digital health standards are foundational to enabling safe, secure, and meaningful exchange of health information across care settings. They underpin the design and operation of digital health solutions, ensuring that data flows accurately and consistently between providers, systems, and consumers. The Standards Framework recognises that while significant progress has been made, a unified national strategy is essential to overcome fragmented adoption and realise the full benefits of connected care.

By strengthening interoperability of health information, the Standards Framework plays a critical role in enabling consumers to trust and confidently use their own health information, whenever and wherever they need it. With over 24.9 million My Health Records, Australians are better equipped to share decisions and manage their health and wellbeing, when they have timely access to their health information.¹ Clear, reliable and connected digital health records empower individuals to participate actively in their care, make informed decisions and move safely between services.

Ensuring that consumers can depend on the accuracy, accessibility and security of their health information is essential to building a person-centred digital health system and fostering long-term public trust in digital technologies. The national adoption of standardised clinical terminology and digital health standards also provides a safer foundation for the responsible introduction of artificial intelligence (AI) tools across the health sector.

The Agency's stewardship role is central to this effort, providing leadership, governance, and coordination across government, jurisdictions, industry, standards development organisations (SDOs), and the broader healthcare community. The Standards Framework outlines the Agency's vision for a dynamic, collaborative digital health standards ecosystem that evolves with Australia's health needs and supports a learning health system.

Clinical engagement is key to enable digital solutions and systems are grounded in real clinical workflows and are trusted to enable the delivery of safe, high-quality care. When clinicians help shape requirements and design, potential safety issues and usability challenges are identified early which can lead to more practical and effective tools. Engaged clinicians also act as champions for change, building confidence among their peers and fostering a sense of ownership that drives sustained uptake and appropriate use.

The Standards Framework directly supports Outcome 1: Digitally Enabled Health System in the *National Digital Health Strategy 2023–2028*² (the Strategy), by providing the foundational infrastructure needed to realise a connected, person-centred, and digitally enabled healthcare system. The Strategy envisions a future where individuals have access to timely, secure, and meaningful health information, and where digital technologies empower consumers and providers alike.

By establishing a nationally coordinated approach to standards adoption and implementation, the Standards Framework enables interoperability across systems, enhances data quality and safety, and accelerates the integration of emerging technologies such as artificial intelligence (AI) and genomics. This includes supporting safe and effective AI use by providing high-quality structured data and consistent terminology across systems.

¹ <https://www.digitalhealth.gov.au/initiatives-and-programs/my-health-record/statistics> as at March 2026

² digitalhealth.gov.au/sites/default/files/documents/national-digital-health-strategy-2023-2028.pdf

Recognising the evolving role of AI, the national adoption of terminology and coding maps, provides a consistent foundation for AI implementations. This reduces the risk of incorrect or hallucination impacted creation of structured data. As AI standards relevant to digital health emerge and mature, this Standards Framework offers the flexibility needed to ensure AI standards are applied consistently across the Australian health ecosystem.

The Agency's role in stewarding digital health standards includes enabling the safe use of AI through standards adoption and applying this Standards Framework to emerging AI standards relevant to digital health. Ensuring alignment of AI governance and broader standards governance will be essential and must keep pace with the increasing use of AI across the health sector.

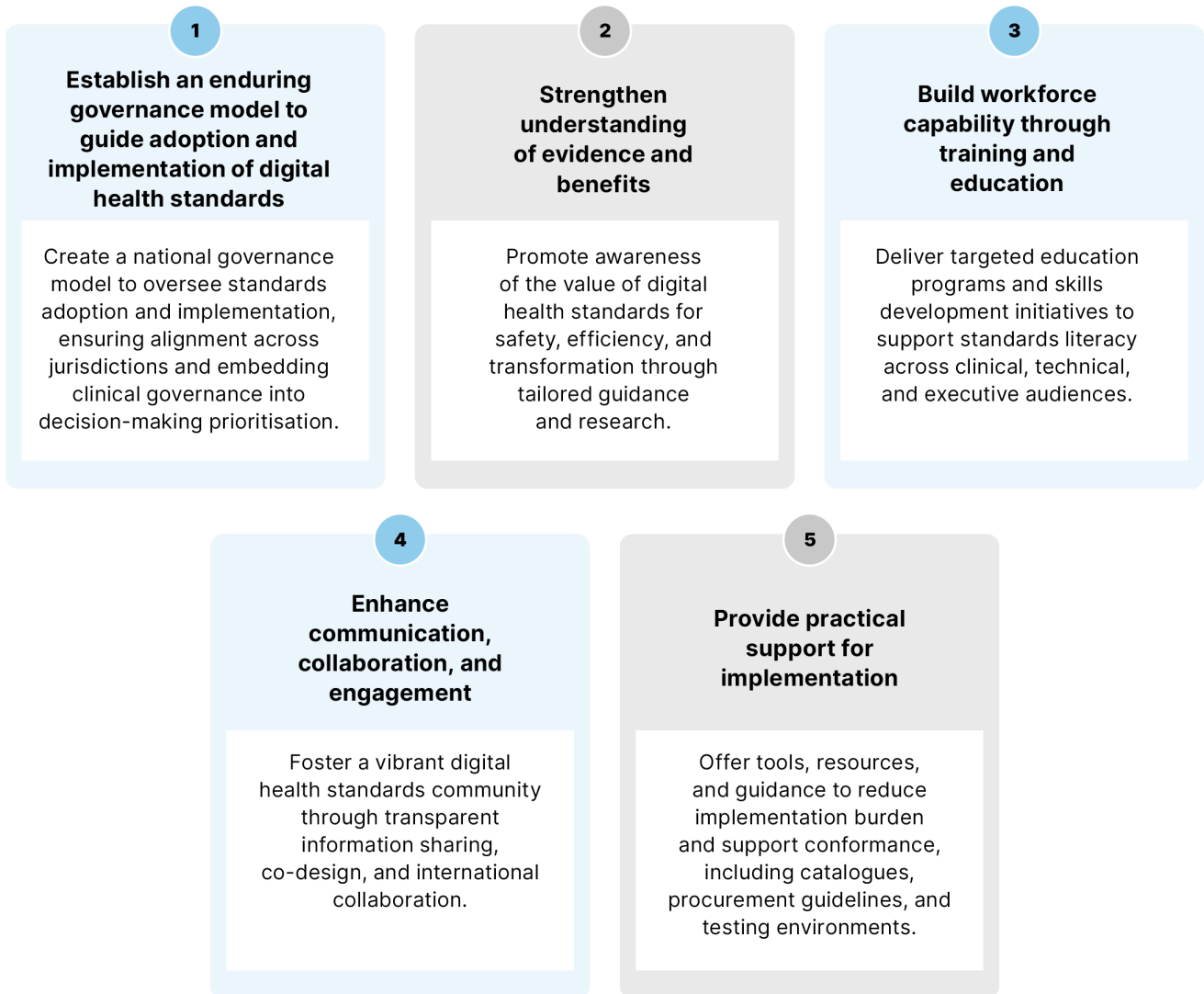
This Standards Framework also operationalises key actions from the *Connecting Australian Healthcare – National Healthcare Interoperability Plan (2023–2028)*³, which identifies standards as critical enablers of real-time data exchange and integrated care. Through initiatives such as the Australian Common Framework for Interoperability (AU CFI) and Health Connect Australia, the Framework supports the development of shared infrastructure, standardised Application Programming Interfaces (APIs), and consistent data models that allow health information to flow securely and meaningfully across the system. This alignment ensures that digital health solutions are not only technically robust and future-ready, but also inclusive, equitable, and responsive to the evolving needs of all Australians.



³ digitalhealth.gov.au/sites/default/files/documents/national-healthcare-interoperability-plan-2023-2028.pdf

Key challenges identified include inconsistent implementation, limited incentives, legacy system constraints, and the absence of a national governance mechanism.

To address these, the Framework proposes five strategic recommendations:



Success will be measured through stakeholder feedback, progress on implementation against the recommendation actions and clinical governance review activities that support continuous quality improvement.

The strategic direction and foundational work delivered under the Standards Framework, will support a safer, more equitable, and digitally enabled healthcare system for all Australians, where health information is accessible and interoperable, and empowers consumers and providers across the health system.



2. Introduction

The Agency has a simple mission – steward and accelerate the delivery of end-to-end connected healthcare for all Australians. ⁴ This will be achieved by ensuring digital services and technologies are underpinned by fit-for purpose digital health standards. Digital health standards provide critical foundations for a safe and strong Australian healthcare system and underpin the vision of connected care by enabling the many parts of the health system to work together.

By strengthening nationally consistent adoption of digital health standards, specifications, information models and terminology, the overall goal is to create an environment where the standards used in technologies promote interoperability and access to information across systems. Adoption of common digital health standards in every health information solution must be the norm rather than the exception. Limited understanding of and experience with standards, often results in the creation of new standards, use of proprietary standards or bespoke solutions that are not interoperable or fit-for-purpose.

Through delivering this Standards Framework, and improved national awareness of standards, problems will be solved leveraging standards, accelerating benefit realisation and whole of system interoperability. This foundational work will enable seamless, meaningful and connected care, and support achieving better and more equitable healthcare outcomes for all.

⁴ <https://www.digitalhealth.gov.au/about-us>

2.1 Purpose

The Standards Framework sets out a unified, nationally coordinated approach to the adoption, implementation and development of digital health standards. The Standards Framework underpins a national program of work on digital health standards being led by the Agency, to ensure a cohesive, standards-based approach to digital health transformation and to drive the adoption of nationally relevant digital health standards.

2.2 Intended audience

The intended audience of the Standards Framework are stakeholders with an interest in how standards are applied in digital health and digital transformation. This includes the clinical community, peak health bodies, policymakers from across government (including jurisdictions), the technical community, software developers and implementers, and public and private health service organisations, whom all play a role in the digital health ecosystem.

As the Standards Framework is delivered, the consumer and clinical voice will be more important than ever, in shaping and advising on the needs and priorities of how our digital health solutions operate. Engaged clinicians act as champions for change, building confidence among peers and fostering ownership that drives sustained uptake and appropriate use. An important step in supporting consumers to participate in this area, is building their understanding of how standards impact their use of digital health solutions and providing them with confidence that the digital health solutions used in their care are safe, secure and a reliable way of managing their health information.

2.3 Scope

The scope of this Standards Framework is wide to encapsulate the broad range of stakeholders involved in delivering healthcare services through digitally enabled tools.

Each healthcare organisation has its own workforce, technology requirements, consumers, reporting, and information needs. As such, this Standards Framework is considerate of the everyday realities faced by healthcare professionals and the administrative workforce that supports them. Effective implementation of digital health standards requires advice and co-design with the clinical and technical community. It also requires the partnership of many organisations, across government and jurisdictions to ensure the policy and strategic levers are in place to support implementation of digital health standards.

2.4 Overview of the Agency

The Agency is a corporate Commonwealth entity established by the Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016.⁵ This Rule outlines the Agency's responsibility to:

- Develop, implement, manage, operate, and continuously improve specifications, standards, systems, and services in relation to digital health
- To develop, monitor and manage specifications and standards to maximise effective interoperability of public and private sector digital health systems
- To develop and implement compliance approaches in relation to the adoption of agreed specifications and standards relating to digital health.

⁵ [Federal Register of Legislation - Public Governance, Performance and Accountability \(Establishing the Australian Digital Health Agency\) Rule 2016](#)

The Agency is responsible for national stewardship, leadership, and coordination of a dynamic, comprehensive, and collaborative digital health standards ecosystem. Core to this work is engaging with Standards Development Organisations (SDOs), industry experts and the broader digital health standards community to identify and deliver the tools needed to guide healthcare in a connected digital future.⁶

The Global Digital Health Partnership (GDHP) defines interoperability as the ability of a system or product to transfer meaning of information within and between systems or products without special effort on the part of the user. Interoperability is made possible by the implementation of standards.⁷ The Agency has taken on a leadership role in driving interoperability through the development of the [Connecting Australian Health Care – National Healthcare Interoperability Plan](#) (Interoperability Plan). The main goal of healthcare interoperability is to support safe, secure, efficient, quality care through a connected healthcare system that conveniently and seamlessly shares high-quality data with the right people at the right time.

The explosion of higher quality health data and its access catalysed through standards, enables analytics and insights that inform changes to models of care that are better for consumers and at a lower cost to the health system.

When a clinical intervention is needed, healthcare providers will have seamless access to the right information at the right time – enabled by interoperability through digital health standards. These standards ensure data flows securely and meaningfully across systems to support informed decision-making and safer care. Over time, the ability to analyse trends in this data will help inform workforce planning and education pathways that align future health professional capabilities to the needs of the health system.

With coordinated adoption of digital health standards, consumers won't need to piece together their health information and story from different systems or care settings. Instead, they will be able to focus on their health and wellness, empowered by their own health information and insights, without the burden of managing fragmented records.

2.5 Consultation

The Agency has consulted a wide range of stakeholders through the Australian Digital Health Standards Advisory Group (Standards Advisory Group) who represent a range of organisations across government, industry, technology, consumer, and clinical areas with an interest in digital health standards. The Standards Framework has also been informed by qualitative and quantitative research.

Prior to the open and online consultation period, a series of workshops were held with the Standards Advisory Group to identify the barriers and enablers to driving adoption and implementation of digital health standards. This group of technical and clinical experts has helped shape the Standards Framework outcomes and the recommendations for supporting adoption and implementation of digital health standards. Targeted consultation sessions were also held with government agencies and SDOs to ensure that the functions and role of organisations are well articulated to support improved understanding amongst users across the healthcare system.

⁶ <https://www.digitalhealth.gov.au/standards>

⁷ Global Digital Health Partnership, 'Interoperability', accessed 17 May 2022.

3. The Agency's role in Digital Health Standards

Digital health standards enable healthcare systems to share information in a consistent, interoperable, and meaningful way, ultimately improving patient care ⁸. The Agency plays a central role in leading, coordinating, and stewarding national efforts to adopt and implement digital health standards. An Intergovernmental Agreement on National Digital Health 2023–2027, committed to by Commonwealth, state and territory governments sets the responsibility for the Agency to support the adoption and implementation of digital health standards and guidelines that promote national interoperability.

The Standards Framework articulates the Agency's role, the importance of coordination and collaboration with the sector of the work required to support the adoption and implementation of digital health standards. The Department of Health, Disability and Ageing (DHDA) plays a critical role by setting national health policy, legislation, and strategic priorities that underpin Australia's digital health foundations, including the broader policy, regulatory, and investment environment in which standards are adopted. DHDA share their vision for long-term data and digital health investment in the Digital Health Blueprint 2023–2033 ⁹, which prioritises strengthening digital health foundations through proactive policy, legislation and standards. DHDA alongside the Agency coordinate efforts to ensure digital health standards are embedded within national reform agendas and digital transformation initiatives targeted at the healthcare system.

Australia's National Digital Health Strategy (the Strategy) 2023–2028 ¹⁰, supported by the Strategy Delivery Roadmap ¹¹, places people at the centre of a connected and digitally enabled healthcare system. It sets a vision and pathway to better serve the needs of Australians today, and into the future, by creating a more connected, person-centred digital health system and realising the benefits digital technology offers individuals, the community, governments, industry and providers. The Standards Framework supports delivery of the Strategy's Outcome 1: Digitally Enabled Health System by providing the national approach for standards adoption and implementation. The specific priority areas of the Strategy that are supported include:

- **Priority Area 1.3:** Enhance and maintain modern and integrated digital solutions, which reflects the expectations of the Interoperability Plan and supports the Strategy Roadmap initiatives
 - **Initiative 1.3.2:** Develop accurate terminology, interoperability standards and conformance for sustained and widespread use (Target: ongoing to 2028).
 - **Initiative 1.3.3:** Develop Fast Healthcare Interoperability Resources® (FHIR®) core standards to support consistent capture and sharing of health information (Target: initiate planning by 2023).
 - **Initiative 1.3.4:** Continue implementing standards and resilience measures to protect personal health information and digital infrastructure from cyber threats and environmental events (Target: ongoing to 2028).

Additional Roadmap Initiatives:

- **Initiative 3.3.4:** Support development of new digital health standards focused on priority use cases and emerging technologies (Target: development by 2027).
- **Initiative 4.1.4:** Participate in global discussions to harmonise standards for health technology exports and reduce costs of customising imported products (Target: ongoing to 2028).

⁸ [Converge or Collide? Making Sense of a Plethora of Open Data Standards in Health Care - PubMed](#)

⁹ [The Digital Health Blueprint and Action Plan 2023–2033 | Australian Government Department of Health, Disability and Ageing](#)

¹⁰ [National Digital Health Strategy](#)

¹¹ [The Strategy Delivery Roadmap](#)

A summary of activity against these initiatives can be found in the Strategy Action and Impact Report 2023–2025 ¹².

Stewardship and Development Functions

The Standards Framework recognises that the Agency may operate across both stewardship and development functions within the digital health standards ecosystem. The Agency’s role centres on coordination across government, clinical and technical communities to identify and endorse national priorities for standards adoption, publishing implementation guidance, and supporting the integration of standards within digital health infrastructure and policy. SDOs such as Standards Australia, HL7 Australia, openEHR, SNOMED International, and GS1 lead the consensus-based technical development and maintenance of specifications, reference materials and tooling within their domain.

While stewardship is the Agency’s primary role, it may lead or participate in standards development activities, in collaboration with SDOs, where there is a clear national need, a policy mandate, or no existing SDO coverage. This delineation maintains clear boundaries between policy stewardship and technical development, while leveraging the deep technical expertise, governance models, and community networks of SDOs, technical experts, and the healthcare community to ensure that standards used in Australia remain technically robust, internationally aligned, and locally relevant.

Open Standards Principles

The Standards Framework reinforces Australia’s commitment to open and commercially agnostic standards principles as a foundation for transparency, participation and interoperability across the digital health ecosystem. Open standards support innovation by enabling collaboration between government, industry, and the community while ensuring health information systems remain adaptable and future focused.

By removing barriers between products and services, open standards allow solutions from different vendors to work together seamlessly. This ensures Australia’s digital health standards are governed transparently, developed collaboratively with a consensus-based approach. They are implemented in a way that builds trust, equity, and confidence in digital health while prioritising consumer choice and ensuring consent is respected in the use and sharing of health information.

Building the infrastructure and processes for ‘how’ information is shared

The AU CFI initiative, developed as an action under the Interoperability Plan, addresses the need to maximise the use of common interoperability patterns, standards profiles, platforms, infrastructure, and processes, when delivering digital health solutions.

The establishment of Health Connect Australia will enable near real-time transfer of health data between systems, providing Australians the ability to more easily share their data with and between healthcare providers, and ensuring consumers are receiving the most effective and informed care when needed. The new data pathways of Health Connect Australia will reduce the need for duplication of clinical information across both a provider’s clinical system and My Health Record by connecting systems directly through API exchanges to share information.

Through collaboration with the DHDA, HL7 Australia and Commonwealth Scientific and Industrial Research Organisation (CSIRO) via the Sparked Accelerator Program, the AU CFI and Sparked products will be leveraged to underpin Application Programming Interface (API) information exchanges. By using standards such as HL7 FHIR, creating new pathways using standardised data transfers across clinical information systems and building repositories, we collectively ensure health data captured in the system is ready to adapt to emerging technologies.

¹² [National Digital Health Strategy Action and Impact Report 2023–2025](#)

Learning digital health ecosystem

A learning digital health system continuously evolves by using data-driven insights to inform improvements in care, policy and system design. To realise this vision, digital health standards need to be tightly integrated with national infrastructure solutions. Standards provide the rules and structure for capturing consistent, high-quality data, while national infrastructure solutions enable the secure exchange and aggregation of that data across the healthcare system.

There are many building blocks needed to create a safe and connected digital health ecosystem. Understanding the role of standards, how they are developed, how they interact with each other, and how they support the healthcare system, is an important role in a learning environment and for harnessing continuous data-driven improvement.

Stewardship of a learning digital health system will ensure there is the breadth of accurate, consistent structured data fuelling continued research and engagement with stakeholders to shape the future and changing nature of digital healthcare.

3.1 Vision for digital standards

The Agency is responsible for national leadership and orchestration of digital health standards. The Standards Framework outlines the need for a collaborative and dynamic environment to support healthcare in its digital transformation using a digital health standards-based approach.

The Agency's objective for digital health standards is to cultivate a dynamic and comprehensive digital health standards ecosystem that enables seamless, safe, and connected care for all Australians. This ecosystem will be built on strong partnerships across government, industry, and the healthcare community, and will continue to evolve in response to changing health needs, emerging technologies, and consumer expectations. By embedding standards into the design and delivery of digital health solutions, the Agency aims to ensure that health information flows securely and meaningfully across the system.

The Agency will realise the objective by leading a nationally coordinated approach to adoption and implementation of digital health standards that:

- Promotes standards as the foundation for interoperability that will connect care;
- Leverages the legislative mandate to steward digital health standards and deliver national infrastructure;
- Coordinates government leadership to catalyse system wide transformation; and
- Supports digital transformation through collaboration and partnership with stakeholders.

The following principles guide the Agency's approach:

 Adopt	 Adapt	 Create
Use established international and domestic digital health standards where available.	Refine international standards where needed to enable them to be incorporated within the Australian health system.	Where no appropriate or suitable standards exist, create them in collaboration with industry, and adopt them as best practice.

Strengthening digital health standards helps make healthcare technology safer and more reliable for both clinicians and consumers. It also ensures that important health data is always available and usable when needed.

When every part of the Australian digital health ecosystem uses the same digital health standards, the value to the entire health system will be much greater than the sum of each of its parts.

3.2 The bigger picture – digital transformation

Digital technologies are intended to ease pressure on healthcare settings, and as highlighted by a Productivity Commission's report¹³, better integration of digital tools and data sharing is essential to improving system productivity and patient outcomes. Through the sharing of accurate and consistent health information, digital systems can inform evidence-based decision-making and support safer transitions of care between healthcare settings. The Productivity Commission report also emphasises that Australia's current health information environment remains fragmented and that modernisation of national digital health infrastructure is critical to realising the full benefits of digital health. A contemporary, data-rich digital health ecosystem is needed to safely support emerging medical science and technologies such as genomics, artificial intelligence, and sensor-based solutions, ensuring these innovations can be scaled effectively and equitably across the health system.

This data-rich environment will also provide improved data analytics to inform self-care, clinical decision making, public health policy and health research to:

- Create an inclusive, sustainable, and healthier future for all Australians through a connected and digitally enabled health system;
- Create a more connected, person-centred digital health system and realising the benefits digital technology offers individuals, the community, governments, industry, and providers;
- Accelerate the development of a thriving health innovation culture and capability to support new and novel health and wellness therapies and treatments; and
- To enable anyone in the healthcare system no matter their location, age, education, race, digital literacy, and knowledge, to be able to access up-to-date healthcare records securely, quickly and easily.¹⁴

This next phase of digital transformation will drive information sharing and advance real time data exchange to make information available when and where it's needed, in line with consumer consent and strong privacy and cyber security standards. People should not have to retell their health story. Their key information should follow them and, should they wish, be available to the whole care team across primary care, allied care, hospital care, aged care, and broader health related services.

The resulting reduced duplication and waste will also decrease workforce and budget pressures and increase safety, quality, and productivity. A thriving, collaborative digital health ecosystem is founded on a common understanding of priorities and direction and relies on settings that support innovation and build confidence and trust. To achieve this, digital health technologies should be developed through partnerships between industry, technology implementers and software industry partners, healthcare providers, researchers, governments, and consumers, supported by agile funding solutions to respond to the rapidly changing digital environment.

¹³ Productivity Commission, 2024, [Leveraging digital technology in healthcare](#), Research paper, Canberra

¹⁴ [National Digital Health Strategy, Australian Digital Health Agency, Accessed August 2025](#)



Strong leadership, cyber security, and governance, including clinical governance, are essential when forming a nationally coordinated approach to the collection and sharing of critical health information, and when creating policy and regulatory settings that encourage partners and collaborators to share cross industry digital expertise.

For successful adoption of digital and other health technologies, confidence, and trust from within the health ecosystem and across the community is required. Stakeholders need to be certain that the use and regulation of digital health is in line with social expectations, and that it will deliver benefits to both individuals and the community, while allowing risks to be managed appropriately.



4. Current landscape

4.1 Recognition of existing digital health standards

The Australian Government has committed to using trusted international standards first, where appropriate, and this commitment underpins the Agency's objective of achieving digital health transformation through standards.

This approach is consistent with Australia's obligations under the World Trade Organization's Technical Barriers to Trade Agreement (DIIS, 2019) and engagement with multilateral global health organisations such as the World Health Organization (WHO), the International Organisation for Standardisation (ISO) and the Global Digital Health Partnership (GDHP). From its inception, the National Electronic Health Transition Authority (NEHTA) and subsequently the Australian Digital Health Agency has been a strong supporter of the work of SDOs such as Standards Australia, HL7 Australia, HL7 International, IHE International, GS1 and SNOMED International, supporting and co-chairing various standards development activities. There has also been an increasing focus on openEHR and the benefits of expressing the clinician voice into data structures. Through these forums, Australia is able to advocate for international rules, norms, and standards that support the wellbeing of the Australian population, while also learning from global best practices and adapting those insights to strengthen domestic policy and implementation.

Australia's commitment to international alignment is also demonstrated through the local adoption of globally recognised standards that support digital health safety and quality. An example of this is Standards Australia's IT-014 Health Informatics national technical committee, that leads engagement across several sectors to support the development of standards for health informatics, information technology in healthcare, and telehealth in Australia. This has seen the development of ISO 81001-1:2021 adopted in Australia as AS ISO 81001.1:2022, an identical adoption that establishes foundational principles for the safety, effectiveness, and security of health software and health IT systems. Similarly, IEC 82304-1:2016 was adopted as AS IEC 82304.1:2022 providing general requirements for the safety of health software products, ensuring that digital health applications used in Australia meet consistent and rigorous international safety benchmarks.

Among these existing digital health standards are nationally recognised clinical standards and terminology frameworks that guide safe, high-quality care—such as the National Safety and Quality Health Service Standards (NSQHS) and SNOMED CT-AU and the Australian Medicines Terminology (AMT) which draw on international best practices to support continuous improvement in healthcare services in Australia.

Despite these efforts, adoption of digital health standards has been sporadic. For example, the former Australian Health Ministers Advisory Committee endorsed SNOMED CT-AU as the national clinical terminology in 2005. This resulted in multiple national policies, programs, frameworks, and specifications recommending use of standard clinical terminologies to record aspects of patient care and transfer information between systems. However, its implementation and use in clinical information systems and digital health solutions is not nationally consistent.

Some health sectors have near-universal use of HL7 v2 for messaging and exchanging of patient and clinical event data between different health information systems which was a foundational step in moving towards interoperability. There is strong support across Commonwealth Government for transitioning towards use of FHIR Standards and allowing systems to exchange data using modern technologies such as APIs, strengthening its implementation across products and services delivered as part of national digital health infrastructure.

Part of this strengthened investment is occurring through programs such as Sparked AU FHIR Accelerator. Funded by the Australian Government, Sparked is a collaborative between the CSIRO, DHDA, HL7 Australia and The Agency. The model is first established outside the United States, and the first that is clinically led. The Sparked community brings together clinicians, healthcare workers, software developers, healthcare organisations, consumers and government agencies that are contributing to the development of interoperability standards for Australia.

4.2 What Australia has accomplished so far

The Department of Health, Disability and Ageing leads national policy direction and supports program delivery for health technologies and digital health capabilities, and advances research to ensure data and technology are used safely for patients, consumers and healthcare professionals. A wide range of federal government organisations contribute to the development, stewardship and application of digital health standards, data, and specifications in Australia. Alongside the Agency, this includes organisations focused on driving improvements in the safety and quality of health care, such as the Australian Commission on Safety and Quality in Health Care (ACSQHC) who promote digital health adoption and implementation through national safety and quality standards across a range of settings, as well as bodies responsible for national health data and reporting, including the Australian Institute of Health and Welfare.

The CSIRO provides critical technical expertise, including its role as a founding partner and leader of the Sparked FHIR Accelerator, established to advance healthcare interoperability through open, community-driven development of FHIR standards, clinical terminology value sets, clinical data models and associated data standards such as the Australian Clinical Data for Interoperability (AUCDI) and national FHIR profiles suitable for the Australian ecosystem (AU Core and AU Patient Summary) that are based on international standards (International Patient Summary). The CSIRO has played a significant role in clinical terminology uplift through the development of Ontoserver, the FHIR-based terminology server that underpins Australia's National Clinical Terminology Service (NCTS).

Broader whole-of-government digital and service design standards are shaped by the Digital Transformation Agency, while pricing and classification frameworks are developed by the Independent Health and Aged Care Pricing Authority. Digital health standards that are used and adopted nationally are further influenced by the operational requirements of services delivered by Services Australia, as well as consumer-facing digital health platforms operated by Healthdirect.

Together, these organisations play complementary roles in ensuring that Australia's digital health ecosystem is safe, interoperable, and aligned with national priorities and international standards.

Australia has established several national systems, solutions, services, and capabilities that can be leveraged to strengthen adoption and implementation of digital health standards:

The Healthcare Identifiers Service supports the unique and consistent identification of healthcare recipients, healthcare providers and healthcare provider organisations.

The Australian Medicines Terminology (AMT) and the Australian extension of SNOMED CT (SNOMED CT-AU) provide standard vocabulary to record and exchange clinical information. SNOMED CT-AU and AMT are available for use through the NCTS and are maintained and released monthly. The NCTS also contains localised HL7 FHIR (Fast Healthcare Interoperability Resources) reference sets and resources for use.

The My Health Record system is integral to clinical workflows and provides an online curation of an individual's key health information. It contains key health information like immunisations, pathology and diagnostic imaging reports, prescription and dispensing information, hospital discharge summaries and more, all in one place. Modernisation of the My Health Record system, which is anchored in FHIR-native approach, aims to build a system that is more robust, secure and adaptable to growth and supports real-time access to information for the patient and the broader care team – anywhere, anytime. The 1800MEDICARE app harnesses the information available in My Health Record to allow consumers to securely access their own

health information, on their device. These innovations empower consumers to fully utilise the benefits of timely access to their own health information, to support shared decision-making and managing their own health and wellbeing.

Electronic prescribing enables prescribers, individuals, and pharmacists to use electronic prescriptions.

The National Health Services Directory (NHSD) enables individuals and healthcare providers to access comprehensive, consolidated, accurate and up-to-date information.

The National Authentication Service for Health (NASH) enables healthcare providers and supporting organisations to securely access, encrypt and share health information.

Provider Digital Access (PRODA) allows individual healthcare providers and healthcare provider organisations to securely authenticate and access online provider services across all government sectors.

The Metadata Online Registry (METEOR) is Australia's repository for national metadata standards for Health, Housing and Community Services statistics and information.

4.3 Challenges with adoption and implementation

Adoption of standards has varied, in part due to the strength of incentives and mandates. Some of the key challenges for adoption and implementation of digital health standards include:

- Owners of digital health systems have considerable discretion in determining what standards they will adopt.
- Commercial incentives for implementers and software industry partners to use proprietary/different standards rather than nationally consistent standards and terminologies.
- Limited policy drivers (legislative, financial) to encourage sector-wide implementation of interoperable solutions and standards.
- The cost of upgrading legacy systems to provide greater interoperability. To support interoperability, existing legacy systems will need to be replaced and/or modernised. The limited resources available in the health system may affect the pace at which these systems can become more interoperable. Business cases to invest in more interoperable systems must recognise the cost of developing and implementing the standards and terminologies that make interoperability possible, as well as associated change management, workforce training and education costs.
- Privacy and security must continue to have high priority as digital systems become more interoperable. Interoperability should not be accelerated at the expense of significant privacy risks or cyber security disruption, as this could lead to unacceptable harm to individuals or organisations and an erosion of trust.
- The absence of a national governance system for endorsing, adopting, and developing information-sharing standards, and maintaining and evolving these standards. This Standards Framework is designed to fill this gap.

Australian software developers also voluntarily use a range of internationally recognised digital health and usability standards that, while not formally adopted as Australian Standards, are widely referenced across government and industry. For example, ISO 9241-210:2019 provides requirements and recommendations for applying human-centred design principles and activities across the life cycle of interactive systems and is commonly used as a practical benchmark to improve usability and user outcomes. Ensuring solutions are designed with the end user, is an important part of ensuring the clinical safety of digital health solutions that are used across our healthcare system¹⁵. However, where a standard such as this is not locally adopted, it

¹⁵ [Using human centred design and human factors to support a rapid health information technology patient safety response | BMC Health Services Research | Springer Nature Link](#)

can create challenges including inconsistent interpretation across jurisdictions and vendors, reduced clarity in procurement and assurance expectations, and fewer nationally agreed reference points for demonstrating conformance in Australian digital health contexts.

A recent review conducted in the UK ¹⁶, found that despite having agreed national standards for digital health solutions in place, supportive systems are needed to ensure they are understood, implemented into the right digital solutions, monitored through national, regional and organisational governance systems and issues that are identified are fed into a quality and risk management improvement system.

An approach is needed to coordinate adoption and implementation of digital health standards for Australia, across government agencies with the clinical, technical and broader community ensure there is a clear and transparent process for national adoption of digital health standards that support interoperability and whole of government digital transformation.

4.4 Benefits of using digital health standards

Implementing standards brings the following benefits:

Enhanced patient safety and data quality

- Better data quality can more accurately reveal patterns of disease and help health systems target interventions and allocate resources more effectively to public health programs ¹⁷,
- Using standard clinical terminology such as SNOMED CT-AU and LOINC-AU, helps make clinical information clear and consistent ¹⁸, so it's less likely to be misunderstood or recorded incorrectly,
- When health information is accurately captured and recorded in a standard way, digital solutions can support clinicians with accurate alerts, reminders, and guidance.
- Enhances care coordination so all providers see the same, up-to-date information, lowering the risk of miscommunication
- Helps minimise clinical risk through consistent and reliable processes, standardised terminology, language and formatting.
- Supports safer transitions of care (e.g., hospital to GP) by preventing lost, incomplete, or misunderstood data.

Better patient experience and outcomes

- People benefit from seeing the same, consistent health information across all their care providers, which improves communication and helps ensure smoother, safer continuity of care.
- Digital standards help advance equity by supporting care models that improve access for people living in rural and remote areas, where workforce shortages constrain service delivery. Harmonised standards make it easier to deliver consistent, high-quality, individualised care for people in vulnerable communities.
- Builds consumer and health care provider confidence that the digital solutions used in the health care system, are safe and reliable, if they conformant to appropriate standards.

¹⁶ [Patient safety issues associated with electronic patient record \(EPR\) systems – a thematic review](#)

¹⁷ [Data quality assessment in healthcare, dimensions, methods and tools: a systematic review | BMC Medical Informatics and Decision Making | Springer Nature Link](#)

¹⁸ [JMIR Medical Informatics - Systematized Nomenclature of Medicine–Clinical Terminology \(SNOMED CT\) Clinical Use Cases in the Context of Electronic Health Record Systems: Systematic Literature Review](#)

Strengthened security and privacy of health information

- Strengthens the safety and privacy of consumer health information by applying consistent security and privacy controls to support secure, consent-driven access to personal health information.
- Stronger authentication and access control by ensuring only authorised clinicians, representatives and systems have access to health information.
- Improves data security and reduces breaches and security incidents in healthcare organisations ¹⁹.

Improved efficiency and cost savings

- Standardisation streamlines clinical workflows by reducing duplication, minimising administrative burdens, and enabling seamless communication between systems.
- Procurement becomes more efficient as health IT systems and software can be evaluated and integrated based on shared specifications and conformance.
- Automation of routine tasks (e.g., test result routing, medication reconciliation) frees up clinical time and reduces operational costs.
- Improved healthcare professional experience through reduced administrative burden, enabling more time for patient care. Standardised, interoperable systems also give clinicians faster access to high-quality information, supporting prompt and effective clinical decision-making.

Simplified and accelerated product development

- Standards create a stable foundation for innovation; vendors can scale solutions across multiple sites without bespoke adaptations.
- Health IT developers can build systems more efficiently when there is clarity about required content, data structures, and interoperability expectations.
- Reducing uncertainty through well-documented standards helps to avoid rework and accelerates time to market for digital health innovations.

Improved international competitiveness

- Products built to Australian standards that align with international frameworks (e.g., HL7 FHIR, SNOMED CT) are more likely to be accepted in global markets.
- Australian implementers and software industry partners can more easily expand into overseas health systems, fostering innovation, investment, and economic growth.

¹⁹ [\(PDF\) The impact of ISO security standards on enhancing cybersecurity posture in organizations](#)

5. Digital health standards explained

5.1 Digital health standards

Digital health standards are the foundational enablers for interoperability and connected care. Although they are often technical in nature, in simple terms, these standards guide solution providers and implementers on consistent data requirements, workflows, interfaces, and methodology embedded within the technology we use in healthcare. Ideally, they are informed by clinically led processes and should always be developed with a focus on ensuring safety, quality and nationally consistent healthcare data quality and workflows across the healthcare ecosystem.²⁰

Interoperability is enabled by the consistent adoption and implementation of standards. These standards enable consistent sharing of meaningful health information accessible to healthcare providers and consumers. It also enables health information to be discovered and exchanged across the healthcare system for secondary use purposes, for example service planning and research. A key challenge is to maintain relevance and compatibility as new standards are created, and existing ones evolve.

Interoperability standards refer to a range of standards artefacts, such as:

- Health information models that describe the structure and context of the healthcare content being exchanged
- Clinical terminology that defines semantically rich healthcare concepts in both human- readable terms and machine-readable codes
- Data and information exchange specifications that provide a standard set of rules for communication between two systems that meet a defined objective or use case
- Identity standards such as unique identifiers for patients, healthcare providers and organisations to support accurate identification and data matching when exchanging health information
- Cyber security standards are also required to support interoperability throughout the digital health system. These are applied across the whole digital health ecosystem and are not specific to interoperability. Using cybersecurity standards strengthens the overall digital ecosystem and enhances confidence and resilience in emerging technologies.

There are numerous national and international interoperability standards, and there has been a significant movement towards adoption of these standards in Australia.

²⁰ <https://www.digitalhealth.gov.au/standards>

5.2 Types of digital health standards

Digital health standards can be categorised by type:

Figure 1. Types of digital health standards.



5.2.1 Information exchange (Transport and messaging)

Definition: Information exchange standards support the formatting and exchanging of messages between healthcare systems. Also known as transport and messaging standards, these are the foundation for the operation of the national My Health Record system and to broader health information exchange initiatives.

Standards and initiatives:

- **HL7 v2:** Widely used across Australian healthcare for system integration and messaging.
- **HL7 Clinical Document Architecture (CDA):** The current national standard underpinning the My Health Record supporting sharing of standard document types.

- **HL7 FHIR (Fast Healthcare Interoperability Resources):** The current international standard format for sharing and exchange of health information. Australia is in the process of adopting and adapting this standard to support modernising its national infrastructure.
- **Secure Message Delivery (SMD):** A national specification for securely transmitting clinical documents (e.g., referrals, discharge summaries) between providers. It includes standards for encryption, authentication, and message packaging.

5.2.2 Terminology and classification

Definition: Structured systems to ensure consistency in representing meaning in health information/medical terminology and classification. Australia adopts internationally recognised classifications along with local adaptations. These support consistent recording of quality clinical information, classification and coding for funding (e.g., Medicare), analytics, and public health reporting.

Standards and initiatives:

- **SNOMED CT-AU:** The Australian local extension of the international SNOMED CT clinical terminology standard. It is maintained by the NCTS and includes computer-readable concepts and user-friendly terms tailored to Australian clinical practice. By providing consistent language for recording health information, SNOMED CT-AU supports safer care, enables tools like clinical decision support, and allows health data to be reused for research, reporting, and system improvement.
- **ICD-10-AM:** The Australian Modification of the World Health Organization’s International Classification of Diseases. It is primarily used for morbidity coding in hospitals and supports classification and coding of clinical documentation, statistical reporting and health system planning. ICD-10-AM codes are grouped into Diagnosis Related Groups (DRGs) underpinning the casemix funding model – a method of allocating hospital funding based on the type and complexity of care provided. These groupings inform Activity Based Funding enabling consistent benchmarking, resource allocation, and performance monitoring across the health system. ICD-11 is the latest (11th) revision of the ICD and has been designed to be interoperable in health information systems.
- **Logical Observation Identifiers Names and Codes – Australia (LOINC-AU):** Used for standardising the reporting of pathology and diagnostic results. Like SNOMED CT-AU, it is maintained by the NCTS, it supports consistent reporting across systems and enables secondary uses such as public health reporting and analytics.
- **Australian Medicines Terminology (AMT):** A component of SNOMED CT-AU, it is a national standard for consistent codes and descriptions for identifying medicines for prescribing, dispensing and clinical documentation. AMT is integrated with PBS listings and supports interoperability, decision support, and safe medication management across care settings.

5.2.3 Security

Definition: Security standards are designed to support trust in systems while aligning with broader information security frameworks. They define the protocols, controls, and practices that protect sensitive health data as it moves across different platforms, providers, and jurisdictions. These standards ensure confidentiality, integrity and availability of data when it is needed.

Frameworks and policies:

- **Information Security Manual (ISM):** Australia's official cybersecurity framework developed by the Australian Cyber Security Centre (ACSC). It provides comprehensive guidance for organisations to protect their information technology and operational technology systems from cyber threats.
- **ISO/IEC 27001:** International standard for Information Security Management Systems (ISMS). This has been widely adopted across healthcare settings for information security management systems.
- **Essential 8:** The Australian Signals Directorate (ASD) has developed prioritised mitigation strategies, designed to mitigate cybersecurity incidents and help organisations protect themselves against various cyberthreats. The most effective of these mitigation strategies are the Essential Eight.
- **My Health Record Security Requirements:** Mandatory conformance obligations and assessments for software developers and implementers connecting to the My Health Record system.
- **Public Key Infrastructure (PKI):** Used to enable secure authentication, digital signatures and encryption for health professionals and systems.

5.2.4 Privacy

Definition: In the context of digital health, privacy ensures the confidentiality, integrity and appropriate use of personal health information. Privacy is governed by both general and health-specific legislation which define how health data can be collected, stored, accessed, and shared. Privacy protections are essential for maintaining public trust and supporting ethical, lawful health service delivery. The Office of the Australian Information Commissioner (OAIC) oversees compliance with privacy laws and provides guidance on health privacy for health service providers.

Legislation and guidelines:

- *Privacy Act 1988 (Cth):* Applies to the handling of personal information, including health data, under the Australian Privacy Principles (APPs), specifically APP 11 mandates protection against misuse, interference and loss. The Act also outlines permitted health situations for collection, use, and disclosure without consent under certain conditions.
- *My Health Records Act 2012 (Cth):* Governs the operation of the My Health Record system, including rules for use, access, and disclosure of information within My Health Record. It includes specific privacy protections and mandatory data breach notification obligations for system participants.
- **State and Territory Health Privacy Laws:** In some jurisdictions (e.g., NSW, VIC), additional health privacy legislation may apply to public sector providers.
- **Health Privacy Guidelines:** Issued by OAIC, these clarify how providers must handle consent, data minimisation, and breach notification. Privacy Management Plans are also recommended by OAIC for all health service providers to proactively manage privacy risks and ensure compliance.

5.2.5 Identifiers

Definition: Identifiers connect the right information with the right individual at the point of care. This gives both healthcare providers and patients confidence that they are using the correct information, wherever and whenever they provide or receive healthcare. Identifiers are represented as a unique number that's assigned to an individual, individual health providers, organisations and devices. Australia has a Healthcare Identifiers Service (HI Service) that assigns unique identifiers and is currently used to support many aspects of digital health, including electronic prescribing, secure messaging and My Health Record. Other identifiers that are used in healthcare settings including Global Trade Item Numbers (GTINs) to identify products, and Global Location Numbers (GLNs) that identify locations and parties involved in the supply chain. These have the ability to support accurate tracking and traceability of health products to an individual or location.

Identifiers:

- **Individual Healthcare Identifier (IHI):** Unique to each person receiving healthcare in Australia.
- **Healthcare Provider Identifier – Individual (HPI-I):** Assigned to clinicians and used to verify credentials.
- **Healthcare Provider Identifier – Organisation (HPI-O):** Identifies the healthcare organisations or practices.
- **Healthcare Support Service Provider – Organisation (HSP-O):** Organisations that do not directly provide healthcare services but provide care and support services to older Australians or people with disability.
- **GS1 Keys:** unique identification of each medicinal product, device, locations, assets. The use of these standards to identify regulated health products such as Medicines and Medical Devices have been included in Australian Therapeutic Goods regulatory standards.
- **ISBT 128 standards:** internationally recognised for the purposes of identifying medical products of human origin (MPHO) such as blood products, cellular therapy, tissues, milk, fecal microbiota and organs for transplant. They improve traceability for the safety of patients and donors and are increasing used globally within the areas of personalised and precision medicine.

5.2.6 Content (Data models and documents)

Definition: Standards for the structure and organisation of data within clinical documents and messages, as well as health information storage for both operational and analytical purposes. Content standards define the structure of documents shared across digital health systems, ensuring that clinical meaning is retained and data is usable.

Standards and initiatives:

- **HL7 CDA (Clinical Document Architecture):** A HL7 standard used for structured documents such as Shared Health Summaries and Event Summaries in My Health Record based on the HL7 Reference Implementation Model (RIM) schema.
- **HL7 FHIR:** A technical standard format for sharing health information consistently, underpinned by modern web-based infrastructure/tools. FHIR includes Resources, Profiles and Implementation Guides.
- **FHIR Resources:** Defined modular units of health data representing real-world clinical information e.g. Patient Resource contains a bundle of data typically required for sharing information regarding a patient.

- **FHIR Profiles:** Localised versions of the international FHIR standard for a specific jurisdiction, for example, in the Australian context - AU Core
- **FHIR Implementation Guides:** A set of instructions of how resources and profiles should be used together for a specific clinical scenario e.g. AU eRequest Implementation Guide – expected data and workflow rules for pathology and diagnostic imaging requests.
- **openEHR:** openEHR is a set of open specifications, and structured clinical information models that define content, structure and clinical context. These are referred to as clinical archetypes and templates. An openEHR archetype is a computable specification for a single, discrete clinical concept. OpenEHR provides a foundation for creating interoperable electronic health records with consistent clinical content and decision support capabilities.
- **Australian Clinical Data for Interoperability (AUCDI):** Is a collection of data groups and data models representing the clinical (patient care) requirements for data entry, data use and sharing of health information supporting patient care. It has been developed by the national Sparked FHIR Accelerator standards community and is underpinned by use of national and international standards such as FHIR and openEHR archetypes.
- **eHealth Specification Library:** Hosted by the Agency, this contains national specifications for content structure across multiple use cases (e.g., pathology reports, diagnostic imaging reports, medication records).
- **Clinical Information System (CIS) Standards:** Consist of a list of technical standards, that share the recommended minimum software requirements for how clinical information should be captured, structured and exchanged.
- **National Minimum Data Sets (NMDS):** A NMDS is a core set of data elements agreed, for mandatory collection and reporting at a national level.
- **Observational Medical Outcomes Partnership (OMOP) common data model:** a standard for viewing longitudinal data for analytical purposes.

5.2.7 Clinical safety

Clinical safety standards are guidelines and requirements that ensure digital health solutions are designed, developed, and used in ways that prevent harm, support safe clinical workflows, and protect consumers. By using these clinical safety standards, they can help inform the way software functions, presents information accurately, supports correct clinical decisions, and manages risks throughout the product lifecycle.

Standards and guidelines:

- **ISO 81001-1:2021 / AS ISO 81001.1:2022:** Health software and health IT systems safety, effectiveness and security — Part 1: Principles and concepts. This standard defines safety and risk-management principles across the entire health software lifecycle.
- **IEC 82304-1:2016 / AS IEC 82304.1:2022:** Health software — General requirements for product safety. Covers safety, quality and secure operation of health software products, especially those running on general-purpose computing platforms.
- **ISO/TS 81001-2-1:2025:** Guidance and requirements for the use of assurance cases for safety and security. Supports structured safety assurance and risk documentation.
- **ISO/TS 20405:2018:** Framework of event data and reporting definitions for the safety of health software. Provides guidance on recording, reporting and analysing safety-related events in digital health.

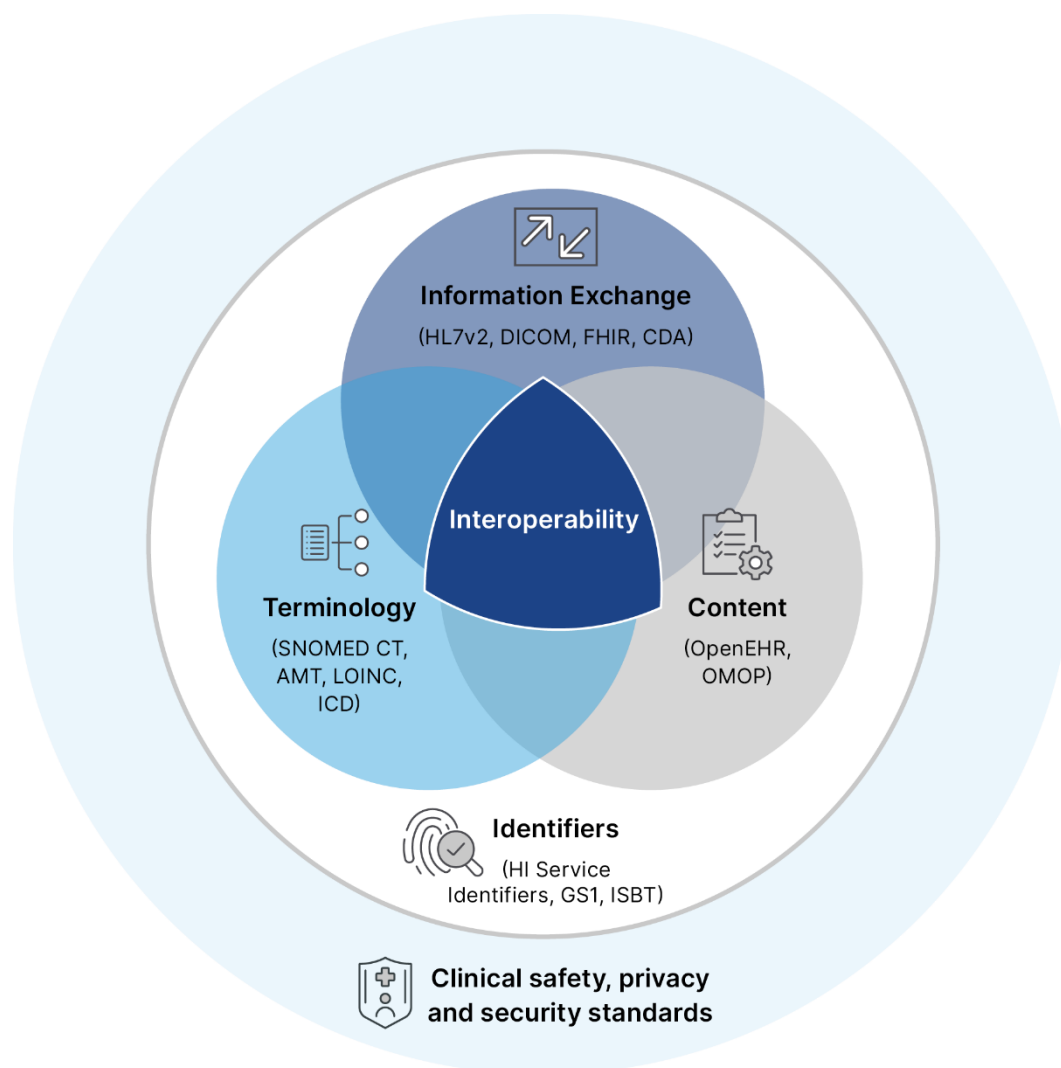
- **AAMI HE75:2009/(R)2018:** Human factors engineering — Design of medical devices. Used to support safe and usable clinical interfaces by reducing user error.
- **National Safety and Quality in Health Service Standards:** Australia's primary national safety and quality standards for all health service organisations.
- **National Safety and Quality Digital Mental Health Standards:** These standards apply specifically to digital mental health services delivered via apps, websites, telehealth, SMS, and other digital platforms.
- **Clinical Care Standards:** outline the care people should receive for specific clinical conditions or procedures, based on best evidence.

5.3 Standards working together

Significant investment has been made to adopt and implement individual digital health standards to address specific use-cases, for example, facilitating real-time data exchange or consistent recording of clinical terminology. However, the Agency has a fundamental role in understanding and coordinating adoption of the range of digital health standards that must come together to comprehensively address the needs of the healthcare system.

No single standard can solve the interoperability puzzle on its own. It is important to note that every standard has different characteristics and strengths and weaknesses. A fundamental aspect of implementing solutions that leverage standards is to understand the different problems that require solving and how the different standards can be combined in those solutions to address the problems.

Figure 2. Standards working together to achieve greater interoperability



This is illustrated with an example in Figure 2 showing how multiple standards are required to support interoperability. In this Figure openEHR provides a framework for modelling clinical knowledge and information, FHIR offers a standard for exchanging this information electronically, SNOMED CT provides a standardised clinical terminology, while ISO provides a framework for integrating digital healthcare systems using these standards. These standards will work alongside identifiers to support accurate matching of information and clinical, privacy and security standards. Interoperability can only be achieved with the use of multiple, coordinated and complimentary digital health standards.

5.4 Clinical governance

Clinical governance ensures clinical safety, quality, and continuous improvement in the delivery of health and care, including through health technologies. Clinical safety is focused on ensuring that products and services are safe for consumers in health and care settings, as well as when individuals managing their own health. To deliver a seamless and clinically safe experience for both consumers and healthcare providers, it is essential that systems are interoperable and properly integrated to support clinical safety and efficiency.

Digital health standards play an enabling role in achieving clinical safety in a range of ways, including:

- Reduction of errors that result from the communication of inaccurate, misinterpreted medicines information.
- Enabling the safe and reliable exchange of health information across healthcare providers and members of the multi-disciplinary care team such as discharge summaries and care plans.
- Preserving the integrity of health information by ensuring secure and reliable data handling
- Facilitate safe and accurate clinical decision support systems through structured messaging so that healthcare professionals and consumers can make informed decisions
- Improved traceability of medicines through defining the requirements for how information about medicines is recorded, shared, and tracked at each stage of the prescribing, dispensing and administering cycle.

Effectively implementing clinical governance promotes clinical safety, quality and continuous improvement in healthcare delivery including through digital health solutions. The Agency's Clinical Governance Framework for Digital Health ²¹ underpins the Standards Framework's approach to supporting the clinical safety and quality of Agency products and services. The Clinical Governance Framework for Digital Health does this under five principles:

- Leading with our people
- System safety and quality improvement
- Evidence-based practice
- Person-centredness
- Partnership.

The Agency's uses a systems-based approach in Clinical Safety Management. A set of guidelines and processes outline how clinical safety services are engaged to ensure Agency digital health solutions are safe for people to use. It is supported by the Agency's Clinical Governance Framework for Digital Health to help digital health solutions meet intended health outcomes without introducing avoidable patient harm. This systems-based approach brings a clinical safety focus to the development and operation of Agency products and services.

In the context of digital health design, clinical safety thinking is about ensuring that digital technologies are safe for clinical use and proactively contributes to reducing unintended clinical risks that may emerge. Under a systems-based approach, there are applicable digital health standards that can be followed for design considerations of digital health products and services to ensure clinical safety. A curated list of these standards is hosted in the Agency's Digital Health Standards Catalogue. It involves a proactive approach to identifying potential hazards and implementing design strategies to mitigate them. The design of digital health solutions should incorporate relevant guidelines, regulations, or applicable standards into the design process, such as accessibility, on-screen display, human factors engineering, and usability evaluation.

A key partner in supporting the safety and quality of digitally enabled care is the ACSQHC. The ACSQHC plays a leadership role in shaping nationally consistent expectations for high-quality digitally enabled care. The ACSQHC influences patient safety through its leadership in clinical governance, including guidance on the safe design, implementation and use of digital tools such as medication management systems. This role is primarily exercised through the development and maintenance of national safety and quality standards, best-practice models of care, and evidence based national guidance that embed digitally enabled care within clinical governance. Some examples include:

[National Safety and Quality Health Service \(NSQHS\) Standards](#): The NSQHS Standards provide a nationally consistent statement of the level of care consumers can expect from health service organisations. All public

²¹ [Clinical Governance Framework for Digital Health](#)

and private hospitals, day procedure services and public dental practices are required to be accredited to the NSQHS Standards. The primary aims of the NSQHS Standards are to protect the public from harm and to improve the quality of health service provision.

[National Guidelines for presentation of electronic discharge summaries \(EDS\)](#): Building upon technical specifications and document architecture for EDSs, that are under the stewardship of the Australian Digital Health Agency, the Guidelines aim to enhance the overall quality and usability of the EDS and contribute to better patient outcomes at transitions of care.

[Safe and responsible use of Artificial Intelligence \(AI\) in health care](#): AI tools can support a wide range of clinical tasks, improving care delivery, health outcomes, and patient satisfaction. As an emerging technology in healthcare, AI can also introduce new risks to patients. The ACSQHC has developed resources to support the safe and responsible use of AI in healthcare.

[Medication Management at Transitions of Care Stewardship Framework](#): describes a stewardship approach to support safe and high-quality medication management at transitions of care as well as coordinated governance of medication management, reduction of medication-related harm and hospital readmission rates due to errors and miscommunication and improving communication between hospitals and primary and aged care, to enable timely discharge planning and post-discharge medication management follow-up.

The Agency will continue to work with the ACSQHC to support the clinical safety of digital health solutions used across the healthcare system.

5.5 Accessibility and Inclusive Design Standards

Accessibility is a critical component of digital health standards, ensuring that all Australians, including people with disability, older adults, and those with low digital literacy, can access and benefit from digital health services. The Standards Framework supports alignment with the Web Content Accessibility Guidelines (WCAG) and encourages the use of inclusive design systems, such as the NHS Design System, which embed accessibility into every stage of service development, procurement and conformance testing to ensure that digital health solutions are include by design and useable by all Australians. This includes:

- Use of plain language and multilingual support
- Compatibility with assistive technologies (e.g., screen readers)
- Responsive design for mobile and tablet devices
- Clear navigation and interaction patterns.

The Standards Framework recognises that true interoperability extends beyond technical alignment to include equitable access, participation, and outcomes for all Australians. In strengthening the consumer-centric focus, the Standards Framework will consider standards for consumer generated health data including wearables, apps, and remote monitoring technologies alongside digital inclusion metrics that reflect the experiences of rural, remote, First Nations, culturally and linguistically diverse (CALD) populations. This approach acknowledges longstanding health and access gaps and aims to ensure that all individuals can benefit from safe, connected, and person-centred digital health services. Alignment with initiatives such as the Digital Inclusion Index and interoperability principles will guide consistent, inclusive implementation across the national digital health landscape.

5.6 Legislation as a lever for standards

All standards are developed with consideration of impacts and compliance with relevant regulation. Identifiers, privacy and security are specific areas where legislation and regulatory frameworks exist to keep personal information and healthcare identifiers private and secure, along with new services like the national Digital ID

system established under the *Digital ID Act 2024*. Legislative frameworks and data security systems that keep pace with technological developments encourage industry development and innovation. They also make it an ethical requirement for healthcare providers to share an individual's information safely and securely by default. These frameworks and systems will give consumers and healthcare providers confidence that using digital health tools and sharing health information through a better-connected system is safe and secure.

Legislation also has impacts across other digital health standards, for example, the recent requirements for healthcare providers to share key health information to My Health Record by default. The [Health Legislation Amendment \(Modernising My Health Record—Sharing by Default\) Bill 2024](#) (the Bill) proposes to amend the [My Health Records Act 2012](#) and the [Health Insurance Act 1973](#) to establish a legislative framework for requiring certain health information to be shared with the My Health Record system. Pathology and diagnostic imaging providers will be the first healthcare providers required to share test results to My Health Record. This legislation drives adoption and has impacts on the digital health standards that may be required to support this change such as use of a nationally agreed set of consistent clinical terminology.

Internationally there are examples of using legislation to drive standards adoption:

- Canada's Bill C-72 proposes prohibiting data blocking and enforcing interoperability requirements across vendors.
- The US 21st Century Cures Act mandates certified health IT systems to support standardised data exchange using USCDI and FHIR.
- NHS England's Data Saves Lives strategy links funding and procurement to conformance with national interoperability standards.

These examples highlight the importance of aligning legislative levers with standards maturity, implementation capability, and sector readiness.

In the absence of detailed legislation and formal policy frameworks, strong and transparent clinical governance becomes essential to ensure that digital health standards are appropriately designed, consistently applied, and effective in mitigating clinical risk. Robust governance structures provide the authority and oversight needed to assess emerging risks, guide standards development, and ensure that digital health solutions support safe clinical practice. They also help maintain accountability across vendors, implementers, and health services, ensuring that standards remain responsive to evolving models of care, new technologies, and lessons learned from real world use.

Legislation and policy serve as critical levers to drive the adoption of digital health standards. When thoughtfully designed alongside a robust governance system, they instil confidence across industry, healthcare providers, and jurisdictions that investments in standards-based solutions are both future-proof and aligned with national priorities. Co-designed policy frameworks, underpinned by a phased, incremental rollout, practical guidance, enabling tools, and ongoing stakeholder engagement, fosters sustainable adoption and cultivates trust throughout the digital health ecosystem.

5.7 Conformance

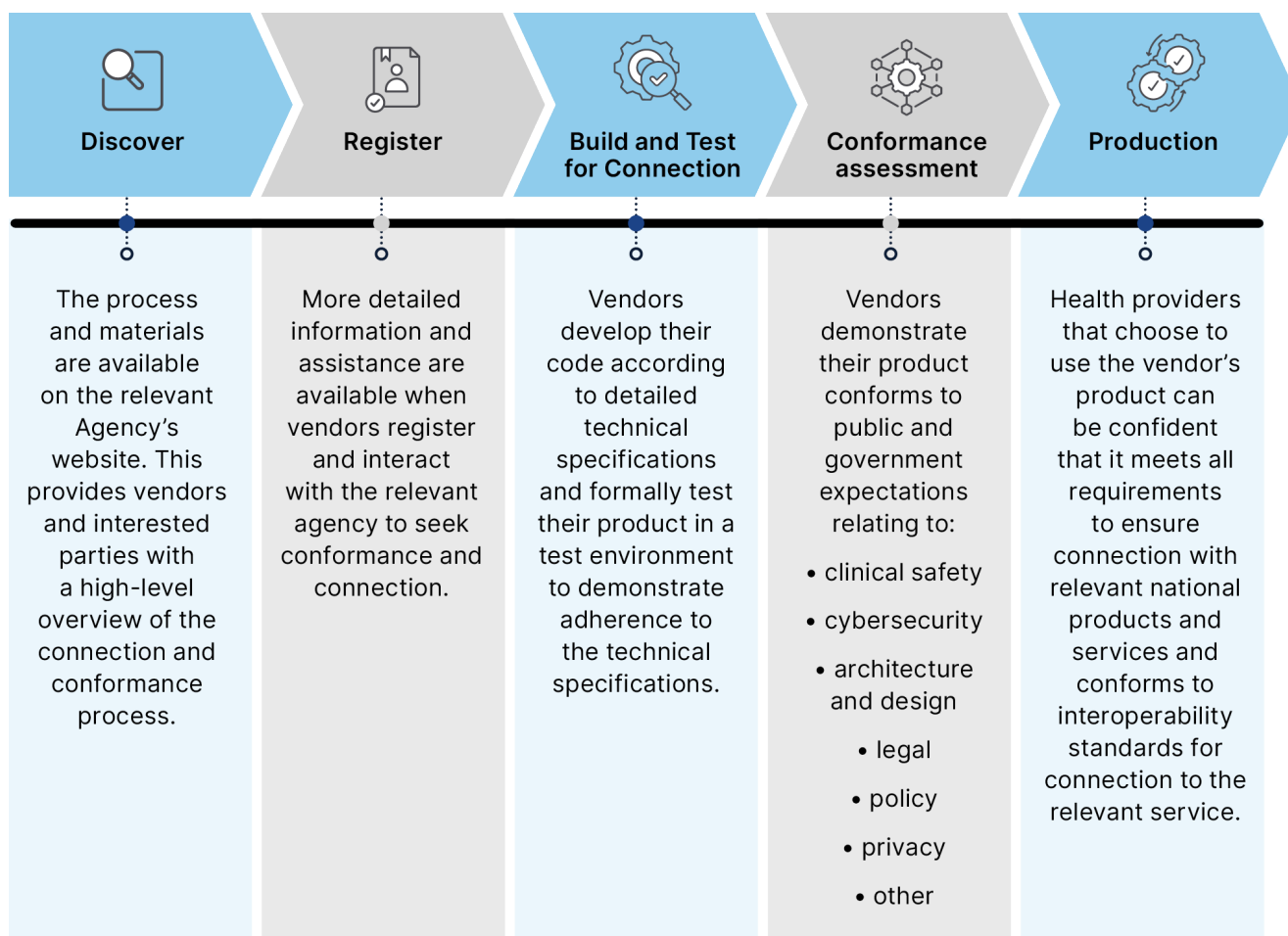
Capturing the relevant legislation and standards that apply to software is part of the Agency's Conformance and Assurance process. At a broad level, conformance refers to the act of adhering to laws, rules, and standards. In relation to software, it means that software conforms with software specifications. When used in the digital health space, conformance means that digital health products and systems operate in a manner that aligns with safety, security, and interoperability expectations. The Agency's [Conformance Framework](#), articulates:

- The objectives and approaches to designing and delivering conformance assessment schemes

- An overview of the scope of conformance and assurance services, including defining key conformance activities, roles and responsibilities and stakeholder touchpoints
- The approach to communicating, engaging and collaborating with stakeholders and consumers of its conformance services.

The health technology developer journey is depicted in Figure 3 and shares the high-level steps in the end-to-end conformance process.

Figure 3: Health technology developer journey through conformance process



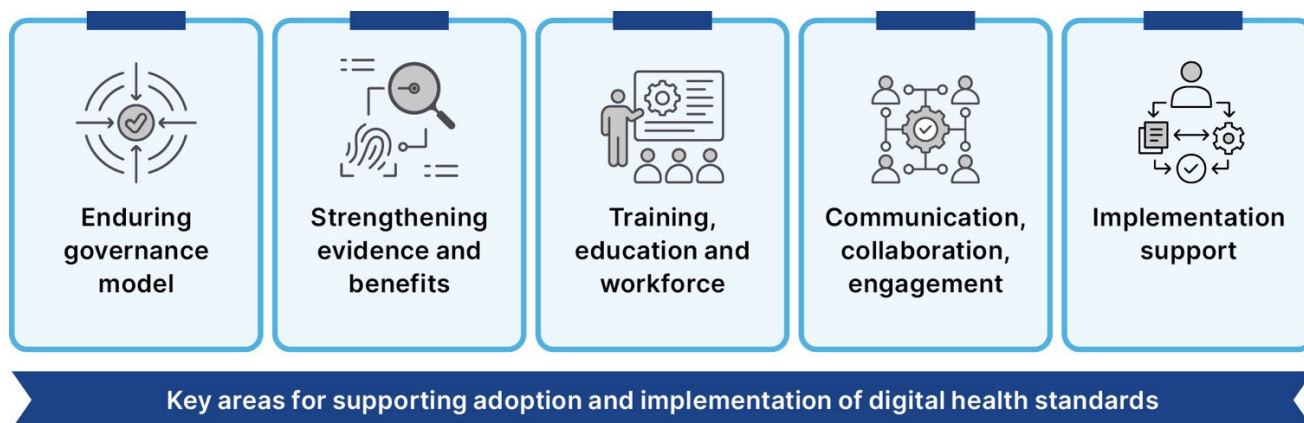
By supporting this area, digital health products and systems are designed, developed, and operated in a manner that is consumer-centred, safe, secure, and interoperable, so that quality trusted healthcare services and information are consistently available where and when they are needed.

6. Recommendations for supporting adoption and implementation

Five key areas have been identified as essential for supporting adoption and implementation of digital health standards. By actioning each of these key areas, The Agency aims to create the foundational structure required to lead future work on supporting adoption and implementation of digital health standards. These key areas are:

- Establish an enduring governance model to guide adoption and implementation of digital health standards
- Strengthen the evidence and the benefits for adoption of digital health standards
- Training, education, and workforce capability uplift
- Communication, collaboration, and engagement
- Provide support for implementation.

Figure 4. Key recommendations for supporting adoption and implementation of digital health standards



6.1 Establish an enduring governance model to guide adoption and implementation on digital health standards

An enduring governance model is built on clear purpose, defined roles and strong cross-sector engagement. There must be alignment between legislation, policy and standards, alongside a collaborative cross-sector leadership. When these elements work together, governance can function effectively, even as standards, digital technologies and priorities evolve.

The [Australian Digital Health Standards Advisory Group](#) provides strategic and technical advice on digital health standards. This group brings together stakeholders from a wide range of organisations (including industry and private health) that have an interest in standards use adoption, implementation and development to support digital health solutions in Australia. A key role of the group is advising on priority areas for future standards use, development and implementation to support digital health outcomes across the country. Advice from the Australian Digital Health Standards Advisory Group is shared with the [Council for Connected Care](#) for visibility of work that supports interoperability of digital health systems.

Recommendations that involve digital health standards to be adopted and implemented across products and services delivered under National Digital Health Infrastructure, these require the endorsement from the Agency's internal governance groups to ensure technical and clinical safety aspects are considered.

The National Clinical Governance Committee for Digital Health provides national clinical governance, system safety and quality, lived experience perspectives and expert clinical advice via the Agency to the Department to consider with the Minister for Health and Ageing and Minister for Disability and the National Disability Insurance Scheme. The membership includes representatives from Commonwealth and state and territory governments, peak bodies, professional associations, consumer groups (including consumers with lived experience) and other stakeholders. This group provides strategic advice and recommendations on legislative, policy, regulatory measures and digital health levers that could be applied for safer care.

A review will be conducted as an outcome of this Standards Framework to evaluate existing national governance arrangements and legislative frameworks that could be utilised to drive adoption and implementation across government. This includes creating a mechanism to facilitate inter-governmental collaboration, and formal endorsement of selected standards as National Government Digital Health Standards. Any proposed governance model will consider appropriate and balanced representation across key stakeholder groups, including consumers, clinicians, technical experts, policy representatives, and other participants as relevant to the scope of work. Consumers and clinicians who use digital health systems must always be included to ensure that standards reflect real-world needs, support safe and effective use, and incorporate lived experience and clinical perspectives.

6.2 Strengthen understanding of the evidence and benefits of digital health standards

A key recommendation from stakeholders is the need to strengthen understanding across the health sector of the evidence and the benefits of adoption and implementation of digital health standards, and their role as a dependency in achieving digital transformation. Strengthening awareness of the evidence and benefits of digital health standards can:

- Improve the understanding of the value of using digital health standards for patient safety, interoperability, and digital transformation
- Improve understanding and confidence in investment on digital health standards
- Inform training and education of digital health workforce.

To strengthen stakeholder understanding of the evidence and benefits of adoption and implementation of digital health standards, the Agency will integrate the evidence and benefits into communication and engagement activities tailored to key stakeholders.

6.3 Training, education and workforce capability uplift

Core to the effective implementation of digital health standards is ensuring that there is sufficient capability, capacity and understanding of standards, their value, and how they are implemented. Stakeholders expressed a need for targeted training to improve awareness of digital health standards and the development of case studies to support their understanding of how digital health standards are used and their benefits.

The Agency's National Digital Health Workforce and Education Roadmap and the National Digital Health Capability Action Plan identified need for a comprehensive baseline standards skills assessment and development plan for digital health standards across Australia. One initiative has included Agency funded development and delivery of digital health standards training. The initial focus is addressing the need for enhanced FHIR skills within the Australian workforce, teaching individuals how to implement and utilise FHIR standards for exchanging healthcare information. A comprehensive training needs assessment will inform skills gaps beyond FHIR and consider measures to address these training needs both in the short term and the longer term.

This training is crucial for ensuring that digital health systems and solutions can effectively share and utilise patient data across different platforms, a key component of interoperability.

Clinical Safety eLearning

The Agency's Clinical Safety and Education Sections are developing eLearning modules on Clinical Safety in Digital Health. This supports the Standards Framework's focus on workforce uplift. The introductory module was launched in August 2025 and is available on the Agency's eLearning platform and received Continuing Professional Development accreditation. An intermediate course is in development. A key learning objective is to help participants recognise Australian standards and regulations relevant to clinical safety in digital health. This initiative strengthens national capability by embedding standards-based digital health safety practices into education and training. It also aligns with the Agency's Standards Framework by promoting consistent, safe digital health practices across the sector. The module links to the Australian Digital Health Standards Catalogue by providing accessible information to support clinical safety in digital health design and implementation. Development has involved collaboration with the Australasian Institute of Digital Health (AIDH), the ACSQHC, jurisdictions, industry, academia, and clinical and consumer representatives.

Training Needs Analysis and Skills Uplift

Building on the Agency's National Digital Workforce and Education Roadmap and National Digital Health Capability Action Plan, an internal training needs analysis has been undertaken to identify capability gaps across Australia's digital health workforce. This analysis drew on targeted stakeholder engagement, workforce consultation, and sector insights to assess current skills and future requirements for adoption and implementation of digital health standards. Findings highlight the need for strengthened capability across priority areas support tailored education pathways for clinical, technical, and executive audiences. The analysis also identified a preference for practical, flexible, and content-specific learning models, including mentoring, Connectathons, and integration of standards education into tertiary and continuing professional programs. These insights inform the Standards Framework's approach to building a scalable and sustainable national training strategy that supports workforce readiness, promotes interoperability, and embeds a culture of continuous learning across Australia's digital health ecosystem.

6.4 Communication, collaboration and engagement

The development of standards is a collaborative process requiring coordination, early and ongoing strategic engagement, clear messaging, dynamic feedback loops, escalation processes through a variety of channels and mechanisms. A diverse and engaged digital health standards community in Australia is vital to ensuring that the standards we choose and use appropriately support the connected care vision.

The Agency has a role in helping to facilitate, coordinate and support the development, adoption and implementation of standards that enable a thriving digital health standards community in Australia to support our future needs. Co-designing approaches with the SDOs and broader health sector is critical to supporting the diverse needs of the digital health community. In addition, actively building the profile of digital health standards and widely promoting their value across the sector is essential to strengthening engagement and ensuring that standards are recognised as a foundational enabler of safe and high-quality digital health.

Communication through access to information and opportunities to share updates

During consultation workshops stakeholders expressed a need for a single and accessible access point for information about digital health standards. This includes having a platform for sharing information about work that's occurring on digital health standards. Key to this is having a clear understanding of the priorities across government for digital health so there is a shared understanding of the direction and timeframes for when stakeholders need to prepare for digital health standards that might be adopted.

The development of a National Roadmap for Digital Health Standards is a key action to be delivered alongside this Standards Framework, to offer guidance on the priorities for digital health standards and the work that is required in response to those priorities. This is particularly important for acknowledging where transitions may be needed from current to new standards and the support mechanisms needed to support stakeholders to transition through these stages. The Roadmap will facilitate improved stakeholder awareness and visibility of work needed to support digital health standards and create opportunities for coordination and collaboration on work needed to support adoption and implementation of digital health standards.

Collaboration and participation in standards development

As technology continues to evolve and Australia's healthcare system adapts to new models of care, the development of new standards and the continual refinement of existing ones remains essential to ensuring safe, secure and interoperable digital health systems. Australia has long recognised that meaningful participation in standards development at an international level is critical to keeping pace with international best practice and ensuring local implementations remain aligned with trusted international approaches.

Australia actively contributes to the work of international SDOs including ISO through Standards Australia, HL7 International, SNOMED International, GS1, openEHR, LOINC and OMOP. Participation in these global communities enables Australia to advocate for national needs, influence the direction of emerging standards, and bring international insights back into the domestic environment to support effective implementation and adoption.

Through collaboration, the Agency endeavours to capture the needs from across a broad range of stakeholders, this includes government bodies, clinical groups, software vendors, research organisations and consumer representatives, to ensure Australian perspectives are consistently represented and continues to identify and create opportunities for stakeholders to engage directly in standards development. The Sparked FHIR Accelerator also exemplifies this collaborative approach, bringing together CSIRO, the Department of Health, Disability and Ageing, HL7 Australia, and the Agency to accelerate the development and localisation of priority FHIR-based interoperability standards for national use.

The [Australian FHIR Management Framework](#) and [Australian FHIR Community Process](#) further strengthen this ecosystem by providing a structured, transparent process for individuals, groups and organisations to develop FHIR-based specifications that are consistent, certifiable and aligned with global HL7 and other standards communities. Certification via this process supports the emergence of trusted artefacts and compatible certification programs that give industry confidence when implementing FHIR at scale.

Collaboration also extends beyond technical specifications to supporting community adoption and implementation. The Agency continues to drive awareness and engagement guided by the Guiding Principles for Digital Health Standards, developed in partnership with Australia's standards and interoperability community. These principles outline expectations for positive participation in standards development and provide a foundation for the Agency's working relationships with SDOs, including processes for standards development, prioritisation, selection and ongoing maintenance.

Through coordinated national engagement, active international participation and strong partnerships across the health and technology sectors, Australia is positioned to continue shaping and adopting the standards necessary to support a safe, connected and interoperable digital health ecosystem.

Strengthening engagement with the digital health standards community

The Agency has a role in supporting and expanding representation and engagement in the digital health community. Part of this role involves strengthening stakeholder understanding of the value and benefits of using digital health standards, within the industry and implementer community and beyond.

Collaboration and knowledge sharing between international jurisdictions is also foundational to supporting international interoperability efforts. The Agency will also strengthen international collaboration with peer local and international jurisdictions. This includes sharing lessons on standards governance, certification, and

adoption and implementation support, and aligning where possible to global standards frameworks (e.g. HL7 FHIR, SNOMED CT, openEHR) to support cross-border interoperability and global collaboration.

Meaningful engagement from consumers and clinicians is essential to the digital health standards community, as their lived experience and frontline clinical insight ensure that standards are usable, safe, person-centred, and grounded in real-world practice. This engagement could be supported through workshops, public consultations, lived-experience advisory groups, clinical reference groups and providing the support to actively participate in these forums.

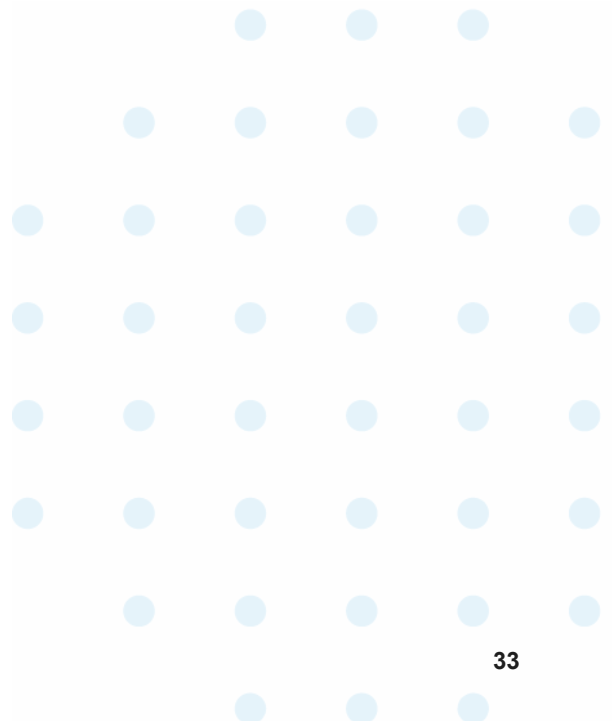
6.5 Provide support for implementation

The Agency recognises that consistent implementation and conformance with digital health standards require practical, transparent, and scalable support. To strengthen adoption across the sector, the Framework includes targeted measures that reduce the implementation burden for software developers, vendors, and healthcare organisations.

This includes providing clear transition signals, practical tools, and guidance to support planning and phased implementation.

Collaboration with SDOs will remain central to this approach, ensuring that implementation and conformance guidance is aligned with international best practice while remaining relevant to the Australian context. By embedding compliance and support mechanisms within a nationally coordinated framework, the Agency will enable partners to confidently meet technical and policy expectations – driving a more consistent, connected, and trustworthy digital health ecosystem for all Australians.

Recommendation 5 in Table 1, shares many of the tools and resources available to support our stakeholders to implement and use digital health standards. There are a range of tools and resources and products available from the Agency that offer support for different types of stakeholders to use and implement digital health standards including the Procurement Guidelines, Digital Health Standards Catalogue and the National Clinical Terminology Service, conformance and compliance capabilities. Improvements to the way these tools and resources are accessed is a recommendation of this Standards Framework and will be considered in the approach to strengthening access to information about digital health standards.



6.6 Recommendation Summary

Table 1: Recommendations and actions for adoption and implementation of digital health standards

Recommendation 1: Establish an enduring governance model to guide adoption and implementation of digital health standards

Key actions to supporting this area include:

1. Establish a framework for governance of digital health standards.
 - Review of existing governance groups and pathways for adoption and implementation of digital health standards across government and jurisdictions
 - Propose a model governance structure to oversee adoption and implementation of digital health standards, including consideration to clinical governance principles and requirements
 - Define what each group is responsible for and how they fit into the standards development, adoption and implementation lifecycle
 - Establish a process or national criteria to guide selection of digital health standards that are applicable for national implementation, considers impacts on clinical governance and clear transition signals to support sector planning
 - Evaluation process for ensuring the proposed governance framework continues to meet stakeholder needs and is adaptable to changing digital health priorities and evolving standards.
2. Create a mechanism for capturing priorities for digital health standards, including priorities of clinical governance, and ensuring these are reflected in a Roadmap to encourage alignment of work and priorities across government.

Recommendation 2: Strengthen understanding of the evidence and the benefits for adoption of digital health standards

Key actions to supporting this area include:

1. Develop guidance for different types of key stakeholders to understand the evidence and benefits of using digital health standards including:
 - Clinicians and healthcare providers
 - Consumers
 - Health service managers including Boards and leadership
 - Software implementers and industry partners.
2. Continue research on the evidence and benefits of digital health standards and research on international best-practice.
3. Utilise information gathered to inform activities under 'Communication, collaboration, and engagement.

Recommendation 3: Training, education, and workforce capability uplift

Key actions to supporting this area include:

1. Undertake a needs analysis to understand the training and education needs and use this inform structured capability uplift initiatives
2. Work with relevant organisations to provide training and education on digital health standards and topics identified in needs analysis
3. Promote training and education opportunities for stakeholders with an interest in digital health standards

Recommendation 4: Communication, collaboration, and engagement

Key actions to supporting this area include:

1. Create a standards information hub that provides a central access point for stakeholders to access information and guidance on development, adoption, and implementation activities to support digital health standards
2. Provide a platform for stakeholders to engage in a community of practice on digital health standards sharing lessons learnt and opportunities to collaborate with others
3. Work with key stakeholders to identify communication needs and identifying opportunities to tailor information to specific audiences including case studies to demonstrate the value of using digital health standards
4. Create a mechanism for stakeholders to share priorities for digital health standards and sharing the national direction for digital health standards through on-going collaboration on the Digital Health Standards Roadmap.

Recommendation 5: Provide support for implementation

The Agency will promote awareness of tools and initiatives available to support stakeholders to implement digital health standards including:

Digital Health Standards Catalogue

The purpose of the Digital Health Standards Catalogue is to provide easy, curated access to the digital health standards that support the ongoing digital uplift of Australian healthcare and ensure interoperability of systems and data.

As one of the many tools provided under the Digital Health Standards Program, the focus of the catalogue is to ensure that digital health standards and specifications are agreed and can be easily adopted.

[The Digital Health Standards Catalogue is available on the Agency's Digital Health Implementer Hub here.](#)

Recommendation 5: Provide support for implementation

Procurement Guidelines

The purpose of the procurement guidelines is to support organisations in choosing solutions, or organisations developing solutions, by identifying the minimum required standards needed in each solution.

The procurement guidelines are accessible via the link below.

[Procurement Guidelines are available on the Agency's website here.](#)

National Clinical Terminology Service

The National Clinical Terminology Service (NCTS) manages, develops, and distributes national clinical terminologies and related tools and services to support the Australian healthcare community.

The NCTS provides state-of-the-art terminology services that promote implementation and adoption of national clinical terminologies in Australia. The aim of the service is to support easier, consistent, and more meaningful use of clinical terminologies in healthcare.

[The NCTS is available on the Agency's Digital Health Implementer Hub here.](#)

Development of minimum system requirements with tailored advice for high priority sectors

The Agency is committed to establishing a common set of core minimum system requirements to ensure digital health solutions remain robust, secure, and interoperable—while still allowing room for innovation, flexibility, and person-centred design.

By defining clear minimum expectations, systems can align with national priorities without restricting innovation or sector-specific needs. Alongside these core requirements, the Agency will provide tailored guidance for high-priority sectors to support specialised functionality, regulatory alignment, and emerging technologies. This dual approach ensures consistency where it matters most, while empowering sectors to evolve and innovate in ways that best serve their communities.

Clinical Information System Standards have been developed for the aged care sector in response to recommendations from the Royal Commission into Aged Care Safety in Quality. The Aged Care Clinical Information System (ACCIS) Standards aim to support a single source of truth that enables consistency and interoperability across a range of care settings. The ACCIS Standards will be a significant enabler for interoperability within the Aged Care sector and its intersection with peer health services. This is a precursor to a more connected, safe, and interoperable sector.

[Information about the ACCIS is available on the Agency's website here:](#)

Conformance Testing and Assurance

At a broad level, conformance refers to the act of adhering to laws, rules, and standards. In relation to software, it means that software conforms with software specifications. The Agency delivers a conformance and assurance function to ensure that digital health products and systems operate in a manner that aligns with safety, security, and interoperability expectations. The Agency's [Conformance Framework](#) describes the process for how conformance testing and assurance occurs. The Agency also publishes the [Australian Register of Conformity](#) as a service for third party vendors, health service providers, hospital or State and Territory health departments to declare the conformance of their systems to digital health specifications and standards. The evolution of the Agency conformance functions is directly informed and enabled by the increasing maturity of digital health standards in Australia.

Recommendation 5: Provide support for implementation

Community connection and testing events

Hosting events such as Connectathons, and other technical implementation and testing focused activities to support software developers and industry partners with the environment to test interoperability and conformance with products and services under national digital health infrastructure.

Standards Development Organisations around the world already host events that focus on their specific standard and scope of practice.

The Agency's vision is to partner with SDOs to deliver testing events and Connectathons that strengthen the digital health standards community. These events bring together all necessary digital health standards in a coordinated way, focusing on national-level benefit realisation and alignment with information-sharing approaches such as Health Connect Australia, the Australian Common Foundation for Interoperability, and as implemented in the modernised FHIR native My Health Record platform.

7. Implementation and delivery approach

Implementation of this Standards Framework will be led by the Agency and delivered through coordinated collaboration with DHDA and other Commonwealth agencies, state and territory governments, SDOs, industry, clinical bodies, researchers and consumers.

A collaborative approach is essential because digital health standards must work across many organisations, systems and clinical environments; no single body holds all the levers, expertise or perspectives needed to ensure standards are useful, implementable and trusted. By bringing these partners together, the Standards Framework fosters shared ownership of national interoperability goals, ensures standards are aligned with international best practice, policy and legislative settings, and balanced with the needs of stakeholders across the health sector.

Collaboration also ensures that technical design is informed by real-world clinical workflows, operational context and lived experience, resulting in standards that are safer, more usable and more responsive to the needs of consumers and clinicians. Partnerships with SDOs strengthen alignment with global best practice, while engagement with industry and implementers helps ensure standards are practical to adopt and can be scaled across diverse digital health solutions. Taken together, this collaborative model builds the collective capability and accountability required to implement digital health standards effectively and sustainably, ensuring that national interoperability is delivered in a way that is fit for purpose, future-focused and grounded in the needs of Australia's health system.

8. Measuring Success

To support the Agency to measure and track progress of the outputs of this Standards Framework, the following activities will be undertaken:

- Progress report that shares an update on implementation of the Standards Framework recommendations.
- Learning from stakeholder feedback via pulse checks and consultation workshops to measure experience of implementation support that has been introduced to support adoption and implementation of digital health standards.

These activities will work alongside broader community engagement activity the Agency is establishing. Together these activities will support a comprehensive understanding of the progress and experience of supporting adoption and implementation of digital health standards in Australia and be used to guide future improvements to the work that is needed to lead and guide our stakeholders toward shared goals for digital health standards.

9. Technical Considerations and Future Alignment

The Framework acknowledges that digital health standards are evolving rapidly alongside new interoperability models, technologies, and data exchange mechanisms. In addition to established standards, modern interoperability approaches now encompass workflow standards, APIs, and implementation specifications that support real-time data exchange and integrated care delivery.

Consideration will also be given to the establishment of an innovation sandbox or testing environment to enable vendors and researchers to evaluate emerging technologies against existing digital health standards in a controlled, transparent manner.

The Agency will maintain a defined review cycle for the Standards Framework, ensuring that governance and conformance pathways evolve in response to sector feedback, standards maturity, and emerging technologies. The cyclical approach will provide clear timeframes for updates, ensuring that Australia's digital health standards ecosystem remains contemporary, evidence-based, and responsive to innovation.

