Australian Government
Australian Digital Health Agency

Conformance Framework

Connecting Australian Healthcare
National Healthcare Interoperability Plan

2023–2028

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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, sea and community. We pay our respects to them and their cultures and to Elders past and present.

Acknowledgment to partners and contributors

Thank you to the partners, organisations, healthcare providers and Australians from the general public who participated in the broad consultations and contributed to the development of the Conformance Framework 2024. We appreciate all who gave their time, experience and expertise.

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 has a key role in delivering the Intergovernmental Agreement on National Digital Health 2023–2027, which has been signed by all Australian governments. The Agency delivers cross-jurisdictional priorities, as set out in the intergovernmental agreement.

Along with our partners, the Agency is responsible for leading and coordinating the implementation of digital strategies and priorities including the Connecting Australian Healthcare – National Healthcare Interoperability Plan 2023–2028. Under the Interoperability Plan, the Agency is also responsible for developing an Australian Digital Health Agency Conformance Framework.

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SECTION 1

Introduction

THIS SECTION INCLUDES:

- **Purpose**
- **Intended audience**
- **Scope**
- **Context**

Purpose

The Australian Digital Health Agency provides strategic leadership, builds national health infrastructure and delivers national digital health products and services to support Australia's progress towards a safer and more efficient health system. The Agency takes a lead role in the development, delivery and uptake of digital health to support a connected healthcare system, accessible to all Australians and embraced by healthcare professionals.

The Agency is the custodian and steward of the National Digital Health Strategy, a strategy for all Australians agreed by Australian governments, which guides the coordination of digital health at a national level.

The Agency has responsibility for conformance services across a range of national digital health initiatives delivered by the Agency – such as My Health Record – as well as those delivered or operated by third parties – such as electronic prescribing.

The purpose of this document is to outline the strategic framework and approach to the delivery of conformance and assurance services by the Agency.

This framework aims to provide transparency to stakeholders, instil confidence and build trust in the Agency's conformance and assurance services through:

- articulating the Agency's conformance objectives and approaches to designing and delivering conformance assessment schemes
- providing an overview of the scope of conformance and assurance services, including defining key conformance activities, roles and responsibilities and stakeholder touchpoints

- defining the Agency's approach to communicating, engaging and collaborating with stakeholders and consumers of its conformance services
- outlining the Agency's commitment to continuous improvement, which ensures the delivery of consistent, quality conformance and assurance services.

Intended audience

This document is intended for organisations, programs and people – internal and external to the Agency – that interact with conformance and assurance services delivered by the Agency.

The primary external audience includes:

- health technology developer organisations and service providers
- state and territory government health departments and agencies
- the Australian Government Department of Health and Aged Care
- the Australian Commission on Safety and Quality in Health Care
- Services Australia.

Scope

This document is limited to describing the conformance framework and the high-level approach to providing consistent, quality conformance and assurance services. It does not detail the operational planning and directives or the supporting processes and procedures that enable the delivery of conformance and assurance services.

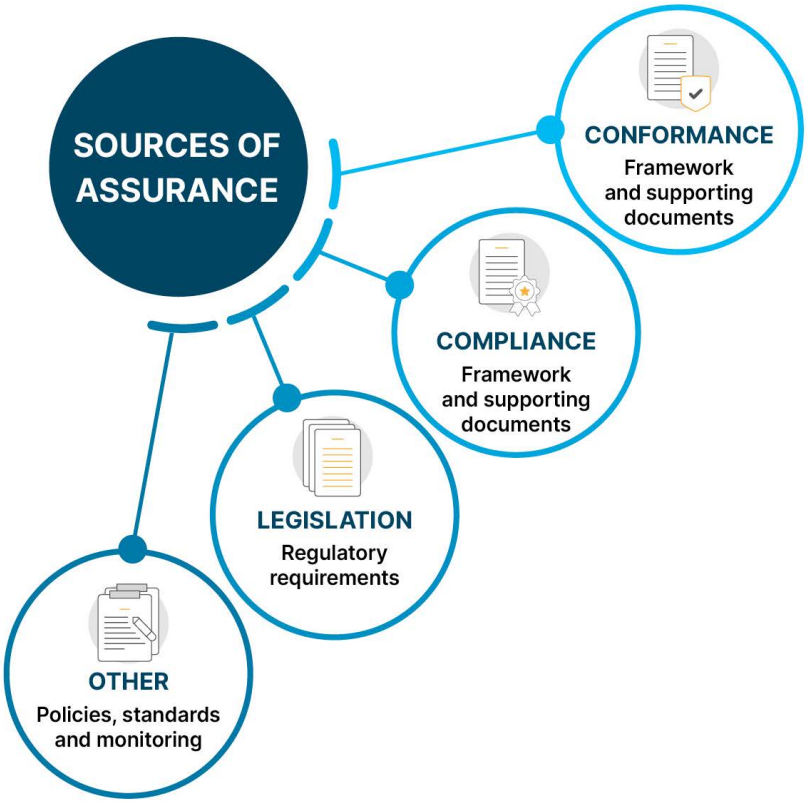
Context

The Agency was established by the Australian Government with a remit to evolve digital health capability through innovation, collaboration and leadership to facilitate digital health integration in the health system. The Agency is the custodian and steward of the National Digital Health Strategy. Our role is to help better connect the health system to further digital health reform in Australia and improve the information that Australian consumers have at their fingertips throughout their healthcare journey. This includes standards stewardship; developing specifications, services and systems such as My Health Record; and building national health IT platforms and systems that work together and enable better flow of information across the entire health ecosystem. Through conformance activities, the Agency can ensure national terminologies and standards outlined in software specifications facilitate data exchange regardless of the systems they use. This puts interoperability at the centre of our drive for quality improvement.

This has also been identified in the National Digital Health Strategy Delivery Roadmap 2023–2028 under initiative 1.3.02: Develop accurate terminology, interoperability standards and conformance for sustained and widespread use.

Robust, fit-for-purpose assurance mechanisms are critical enablers of interoperability. The Agency's approach to assurance for connecting systems is aligned to the Assurance Model (Figure 1) and leverages existing sources of assurance and supporting frameworks to mitigate shared risk. This Conformance Framework is a key component of the Agency's assurance model. It is designed to ensure the consistent design and application of conformance obligations for all software and systems participating in national digital health initiatives, to provide assurance that the identified risks in software and system development and operating behaviour are appropriately mitigated across all known risk areas.

Figure 1: Assurance model



Conformance is Agency core business, and it is an essential activity to support the integrity and stability of the connections and transactions within digital health systems and services. The Agency delivers its conformance services through the establishment and operation of conformance assessment schemes. Broadly, conformance assessment involves the testing, mitigation of risk and validation of the design and operation of a software product to ensure it adheres to standards and specifications that are enforced through conformance requirements. Conformance is concerned with how software is implemented and how it behaves. This is distinct from compliance, which imposes requirements on organisations and people.

Conformance does not end after an initial assessment. Ongoing monitoring of connections to digital health systems and service transactions are necessary to ensure that products continue to operate in a conformant manner. Digital health products are likely to be assessed for conformance many times throughout their life cycle.

Conformance seeks to ensure consistent implementation of standards and/or specifications that may reflect legislative, security, privacy, interoperability and clinical safety aspects of software products that connect to digital health systems and services. Conformance ensures multiple gates exist to protect the integrity and security of national digital health infrastructure and products. This framework has been developed with consideration of this context and the following influencing factors to meet community expectations.

Legislative

The Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016 (Agency Rule) sets out the functions of the Australian Digital Health Agency. Specifically, Part 2, section 9(1) confers a range of functions including 'to develop and implement compliance approaches in relation to the adoption of agreed specifications and standards relating to digital health'.

The Agency also has specific responsibilities for conformance and assurance deriving from a range of legislative instruments that underpin the delivery of various national health programs and initiatives, including:

- My Health Records Act 2012
- National Health (Pharmaceutical Benefits) Regulations 2017 (Cth) and its subordinate instrument Electronic Prescriptions Information Technology Requirements Instrument 2019
- Healthcare Identifiers Act 2010.

Strategic

Under the National Digital Health Strategy, the use of clear and common standards for digital health technologies and data sharing, and regulations that support adherence to conformance standards, are key to interoperability and to realising the benefits of digital health.

The Agency has taken on a national leadership role in interoperability, through development of the *Connecting Australian Health Care – National Healthcare Interoperability Plan* and developing policy tools and governance arrangements to support and accelerate interoperability. Robust conformance and assurance processes are critical enablers of an interoperable digital health ecosystem, ensuring standards and specifications are appropriately and consistently adopted and implemented. By establishing common frameworks, protocols and specifications that enable seamless data exchange and communication between different healthcare systems and stakeholders, the Agency will drive an uplift of the health sector.

Healthcare organisations using healthcare systems that have been assessed for conformance will have confidence that their systems and applications can communicate and exchange data with other systems, regardless of vendor or platform, facilitating interoperability at both the technical and semantic levels.

With the support of all Australian governments the Agency has established the Council for Connected Care, which plays a critical role in driving a community-based approach to establishing the connected healthcare system that Australians desire. The Council comprises stakeholders from all sectors and was established to provide strategic advice on matters related to interoperability, including monitoring progress against the Interoperability Plan's actions and contributing to the annual reporting requirements.

Operational

The Conformance and Assurance team is embedded within the Agency's Digital Solutions Division as a core function of the Connected Care branch. Beyond the design, development and delivery of conformance schemes, conformance and assurance services also provides valuable insight and technical subject matter expertise to a range of programs at various stages – from service and product design, through to incident management. Conversely, the Conformance and Assurance services team depends on subject matter expertise and insight from across the Agency, to inform risk assessments and provide robust assurance in the development of conformance assessment schemes.

While the scope of conformance and assurance service delivery is predominantly internal to the Agency – for Agency programs and products, such as My Health Record – the remit of the Agency's conformance service is expanding to provide services to external stakeholders and programs, such as the Department of Health and Aged Care. The Agency's move towards conformance as a service offering is indicative of the Agency's expertise in conformance service design and delivery and may be an area of growth for the Agency. This will ensure high-quality, efficient, sustainable and consistent conformance services that assure participants of the integrity and stability of a connected Australian healthcare system.

SECTION 2

Strategy and service model

THIS SECTION INCLUDES:

- **Strategic alignment**
- **Conformance and assurance strategy**

Strategic alignment

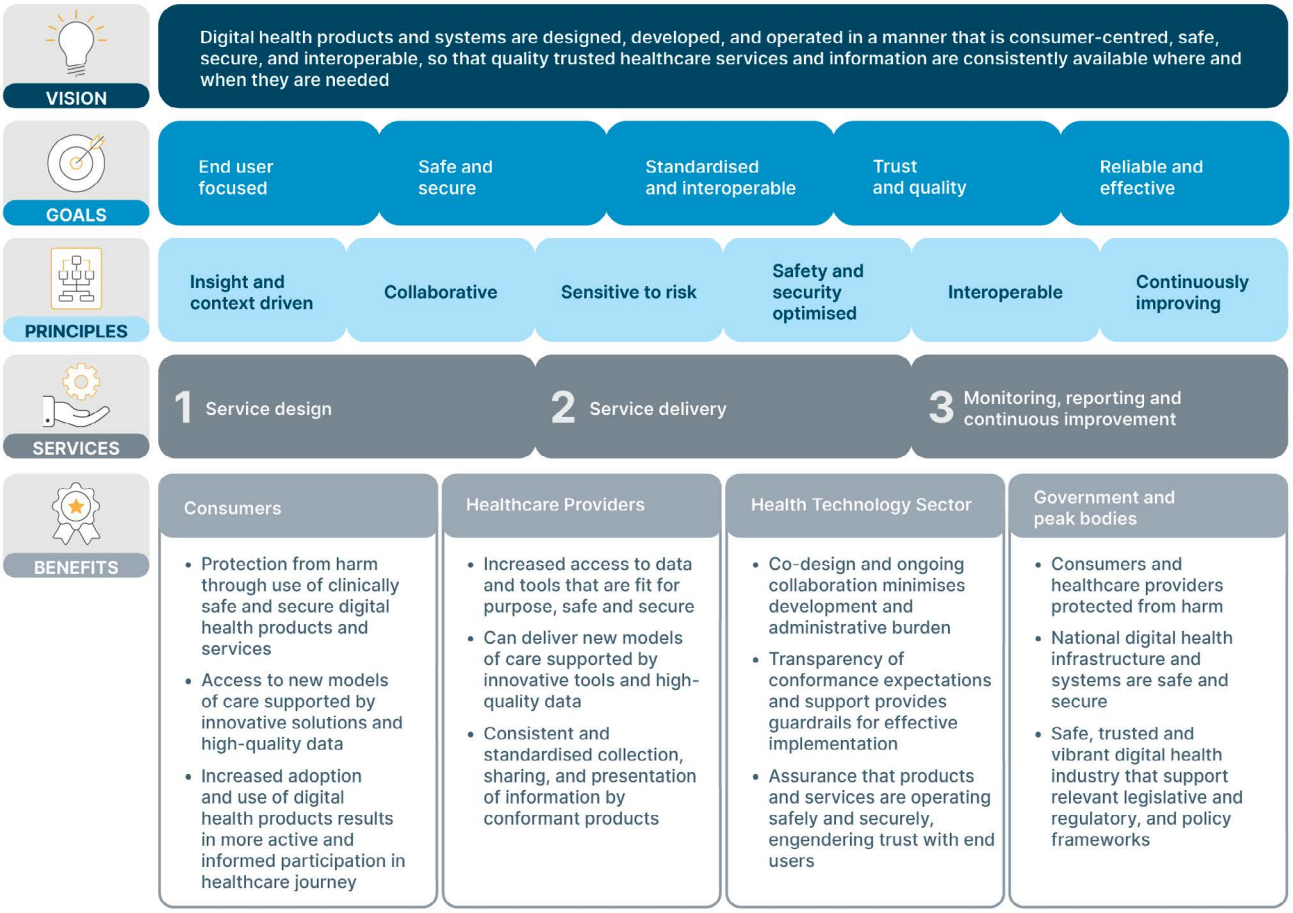
The National Digital Health Strategy 2023–2028 and the Strategy Delivery Roadmap chart Australia's digital health transformation for the next 5 years and beyond. The strategy's vision is an inclusive, sustainable and healthier future for all Australians through a connected and digitally enabled health system.

The strategy identifies 4 change enablers essential for digital health to operate effectively on a national scale and to drive further digital health transformation in Australia. Conformance and assurance activities are a core component of the change enabler 'secure, fit-for-purpose and connected digital solutions' and the priority area 'enhance and maintain modern and integrated digital solutions'.

Conformance and assurance strategy

A well-defined strategic approach to delivering conformance services is crucial for supporting the Agency's mission. Our role involves enabling and providing secure, purpose-driven and interoperable digital solutions. To achieve this, we have developed the Conformance Framework, a strategic model that positions the Agency at the forefront of ensuring standardised and interoperable digital systems. This framework is guided by goals and principles that foster co-design and collaboration with our partners and the health technology sector. By adopting this approach (illustrated in Figure 2), we ensure our processes remain adaptive and responsive in a dynamic environment.

Figure 2: Conformance and Assurance Framework – Strategic approach



Definition of conformance

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 defines conformance as a measurement (by testing) of the digital health products and systems adherence of an implementation to a standard and/or specification.

Conformance follows this approach and takes into account the following factors:

1. **Risk assessment:** Subject matter experts identify and rate risks associated with the software.
2. **Specification of mitigation and controls:** Subject matter experts develop mitigation strategies and controls, which are then documented as requirements for software products and services.

3. **Assessment against requirements:** Software undergoes assessment for conformance against a set of requirements tailored to its specific use cases. This may occur multiple times throughout a product life cycle.
4. **Iterative improvement:** Over time, requirements evolve to enhance the safety of the conformance process and resulting implementations of conformant software.

Vision

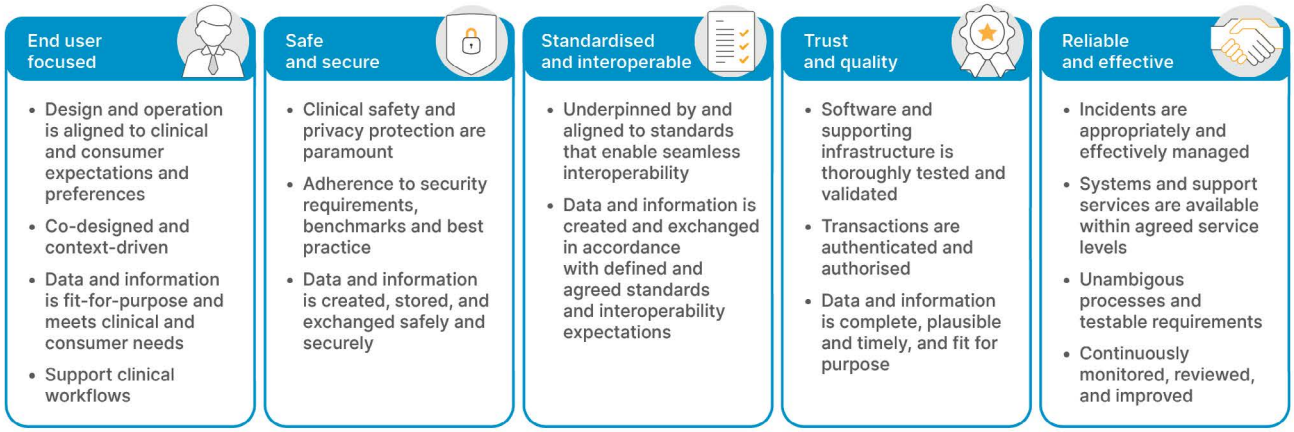
The conformance and assurance vision:

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.

Goals

At a high level, the goal of conformance and assurance is to preserve the safety, privacy and security of consumers and healthcare providers (end users) by ensuring that the digital health products and systems they use adhere to the Agency's conformance requirements and associated Agency, stakeholder and community expectations. Conformance and assurance goals serve to ensure that products and systems are designed, developed and operated in a conformant manner (Figure 3).

Figure 3: Conformance and assurance goals



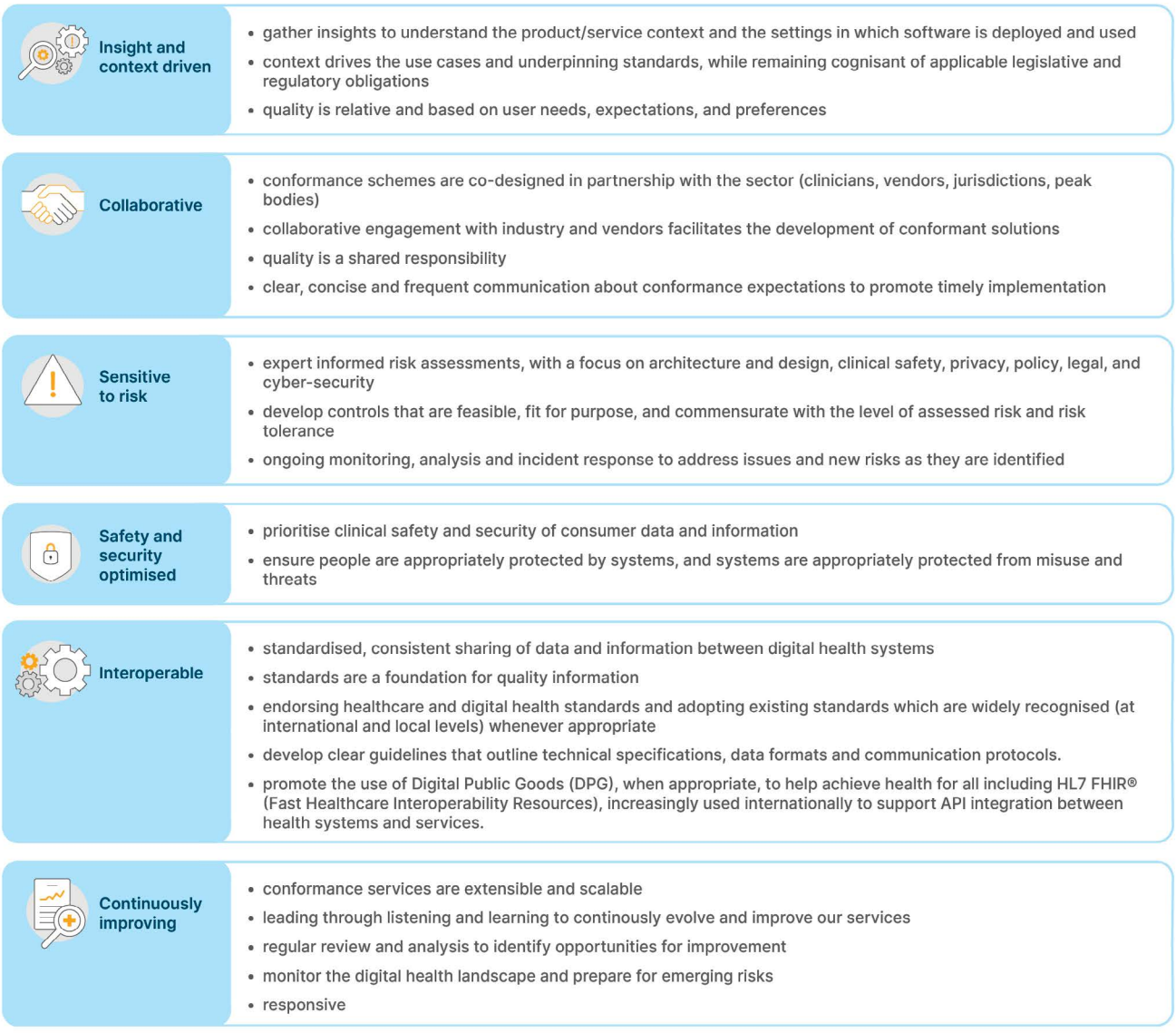
Conformance principles

The Agency adopts a principles-based approach to monitoring and managing shared risks associated with digital health products connecting to national infrastructure and services and connecting to and/or transacting with other third-party infrastructure, products and services.

Adopting a principles-based approach rather than a prescriptive and rules-based approach ensures that conformance schemes are fit for purpose now and into the future. Principles enable conformance schemes to be designed and operated in a manner that recognises the wide variety of health technology developers, products, delivery channels and interactions between digital health systems and services. The approach aligns with the Agency's National Digital Health Strategy to ensure risks are managed through nationally agreed principles and standards.

Six underpinning conformance principles guide the design and delivery of conformance services: insight and context driven, collaborative, sensitive to risk, safety and security optimised, interoperable, and continuously improving (Figure 4).

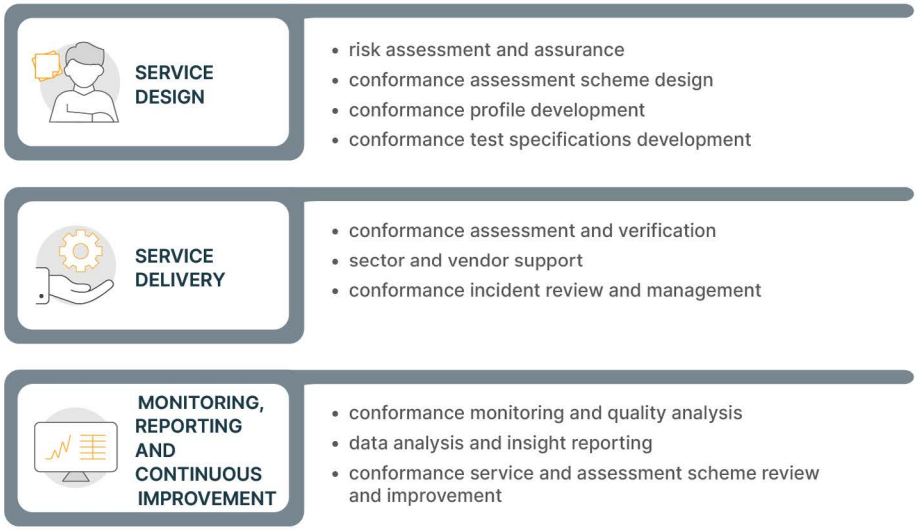
Figure 4: Conformance principles



Conformance services

Conformance and assurance is a core part of the Agency's functions and crosses a wide range of products and services within the Agency and across the health sector. The delivery of conformance and assurance services comprise 3 core functions, depicted in Figure 5.

Figure 5: Core conformance and assurance services



As part of the service design and delivery of conformance services, the Agency may undertake conformance services on behalf of other entities using the service design and delivery approach described above in Figure 5. Any conformance services for other entities will need to be considered on a case-by-case basis.

The following case study on the Aged care Business to Government (B2G) Gateway conformance service is an example of the Agency undertaking conformance services on behalf of the Department of Health and Aged Care.

Case study: Aged care Business to Government (B2G) Gateway conformance service

The Australian Digital Health Agency is working with the Australian Department of Health and Aged Care to deliver improvements to the Aged Care sector in line with recommendations (Recommendation 109) made by the Royal Commission into Aged Care Quality and Safety.

The department will be deploying an Aged Care B2G Gateway system to facilitate the transfer of information from residential aged care facilities to the government with a focus on strengthening quality and safety within the aged care system, reducing administrative burden and enabling near real time data reporting.

The Agency established a conformance service to support the B2G Gateway. The conformance service will ensure health technology developers using the department's B2G Gateway are assessed as conformant to the national digital standards.

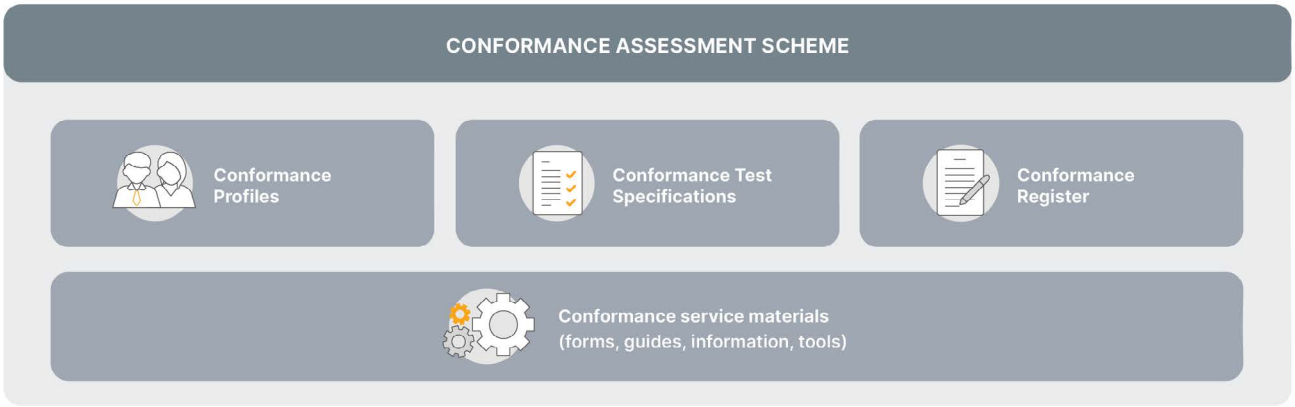
Service design

The objective of service design is to:

- identify, assess and prioritise risks and develop mitigation strategies
- determine the level of assurance required and define the most suitable conformance approach
- ensure a standardised approach to conformance requirements, promoting interoperability across digital health solutions and services
- determine the conformance assessment method
- perform holistic management of non-conformance and mitigate future incident risk through closing identified gaps.

The primary output of the service design phase is the development of a conformance assessment scheme and accompanying conformance profiles and conformance test specifications (Figure 6). A suite of conformance service materials may also be developed, which may vary by scheme.

Figure 6: Conformance Assessment Scheme document map



Conformance assessment schemes define how software will be tested and assessed for conformance and how a product can achieve and maintain conformance throughout its life cycle. It also describes the artefacts, including software and documentation, that support conformance assessment activities. A conformance assessment scheme may comprise one or more conformance profiles.

Conformance profiles comprise the specific conformance requirements. Profiles are typically structured by use cases that describe the type of software/system implementation or the context in which it is used. Conformance requirements are software requirements that are derived to control identified risks for the use cases, through influencing software behaviour.

Conformance test specifications (CTS) are devised in parallel with the development of conformance profiles. The CTS provide a test suite, comprising test cases that are aligned to the conformance profile use cases and requirements. The CTS enables health technology developers to align the products they develop to the conformance profile requirements and self-assess conformance during their product testing.

In addition, during the conformance and assurance service approach, conformance artefacts may be developed to reflect or consider legislative requirements, particularly where a clinical risk may require mitigation.

To ensure that conformance artefacts can be adaptive to user requirements and clinical safety incidents, a modular approach to conformance may be implemented that caters for particular elements or user groups. These modular approaches to conformance can include a particular category of software, such as electronic medication charts, or focus on user groups, such as security conformance. This approach allows the Agency to respond in a more targeted way to change and to lessen the impact for health technology developers. Conformance services, where practical, will develop more modular approaches to assist in responding to change and risk in an evolving environment.

Supporting conformance service materials may include registration forms, conformance declarations, implementation guides and other information and/or tools published by the Agency to help health technology developers adopt conformance requirements into their systems.

Service delivery

The objective of service delivery is to:

- provide support to health technology developers to help them understand their conformance obligations and navigate the end-to-end conformance process
- undertake conformance testing and assessments against conformance assessment schemes
- identify, manage and help to resolve conformance incidents on an individual case basis.

Health technology developers are obliged to ensure products they release to the market are tested and function as intended. They are also required to ensure their products are suitable for real-world use and do not introduce risk of harm or negative impacts from their use.

In some cases, health technology developers may be required to produce test evidence for the Agency to review prior to a formal conformance assessment. Once a health technology developer believes their product is conformant and has met all relevant conformance requirements, they can progress to a formal conformance assessment.

The conformance assessment method for any given conformance assessment scheme will be determined during the service design phase. The selection of an assessment method is informed by the level of risk that needs to be managed and the level of assurance the Agency requires that the risks are appropriately managed. The conformance assessment methods used by the Agency are outlined in Table 1.

Table 1: Conformance assesment methods

Method	Self declaration	Evidence verification	Observed self-assessment	Third-party assessment
Description	Health technology developer tests and self-assesses their product conformance, attesting that it meets all conformance requirements	Health technology developer tests and submits evidence to the Agency to validate and assess the product against conformance requirements	Agency observes health technology developer testing and assesses the product against conformance requirements	Independent assessment conducted on behalf of the Agency by independent entities such as test laboratories or accredited testing organisations

Conformance assessment is required before a new digital health product is permitted to connect to a production environment for its nominated service and commence real-world use. Access to production environments is typically granted by the system/service operator, following notification by the Agency that a product has been declared conformant. Conformance assessments may also need to be repeated as new conformance profiles are published or if conformant product functionality significantly changes. The relevant conformance assessment scheme will outline the circumstances in which a conformance assessment or reassessment is required and any applicable exemption processes.

The delivery of a conformance service is an ongoing, business-as-usual activity. In addition to conformance testing and assessment activities, service delivery also comprises:

- collaborating with internal Agency teams to provide support to health technology developers throughout their conformance journey, including responding to enquiries, hosting webinars or information sessions or publishing supporting material on Agency websites, including the Developer Portal
- managing conformance incidents (where non-conformant behaviour has been identified) and providing support and subject matter expertise for holistic incident management from a conformance perspective.

Monitoring, reporting and continuous improvement

Digital health technology and the maturity of the sector is continuously evolving. Conformance services must also respond and adapt to changes within the sector and the external environment and maintain a view of emerging risks.

The Agency is committed to continuous improvement of its conformance services, informed by insights gleaned from monitoring, analysis and reporting activities.

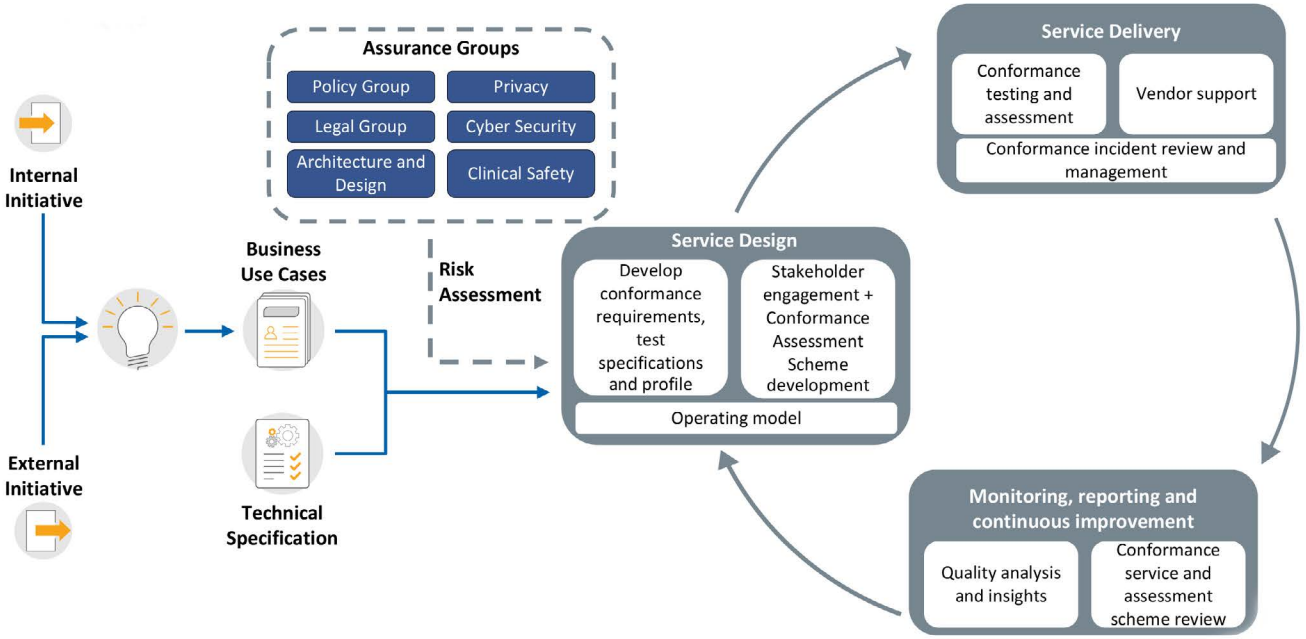
The objective of conformance monitoring, reporting and continuous improvement is to:

- ensure that conformant products and systems continue to behave in a conformant manner and that the intent of conformance schemes is preserved
- identify issues and new or emerging risks that may necessitate strengthening of existing conformance controls
- gather and provide insight to the Agency and its stakeholders on the operation of connected systems and the quality of data and information they transact
- validate whether conformance schemes, artefacts and processes continue to be fit for purpose and make improvements where required
- undertake regular audits of conformant systems to ensure that systems are deployed as tested with the same set of configurations as those granted conformance
- identify and resolve non-conformance with health technology developers, with the view to working collaboratively to bring the system or service back into a state of conformance as soon as possible
- make recommendations to the senior executive and other governing bodies about the deregistration of conformant products that no longer meet conformance requirements.

Data and information about the quality and effectiveness of conformance services are collected from a range of sources and take many forms, including feedback received directly from end users, health technology developers, stakeholders, product/system analytics and transactions. Non-conformance may be detected proactively through routine monitoring and reporting, or reactively through incident management.

Continuous improvement also considers other external factors including changes in legislation, policy, technology, end-user expectations and experience. Improvements to conformance artefacts may also be informed by changes to industry best practice and Agency or government policy and process not directly related to conformance, such as revisions to the Information Security Manual and Australian Government Style Manual. Figure 7 illustrates the conformance service model, including the continuous improvements in conformance.

Figure 7: Conformance service model

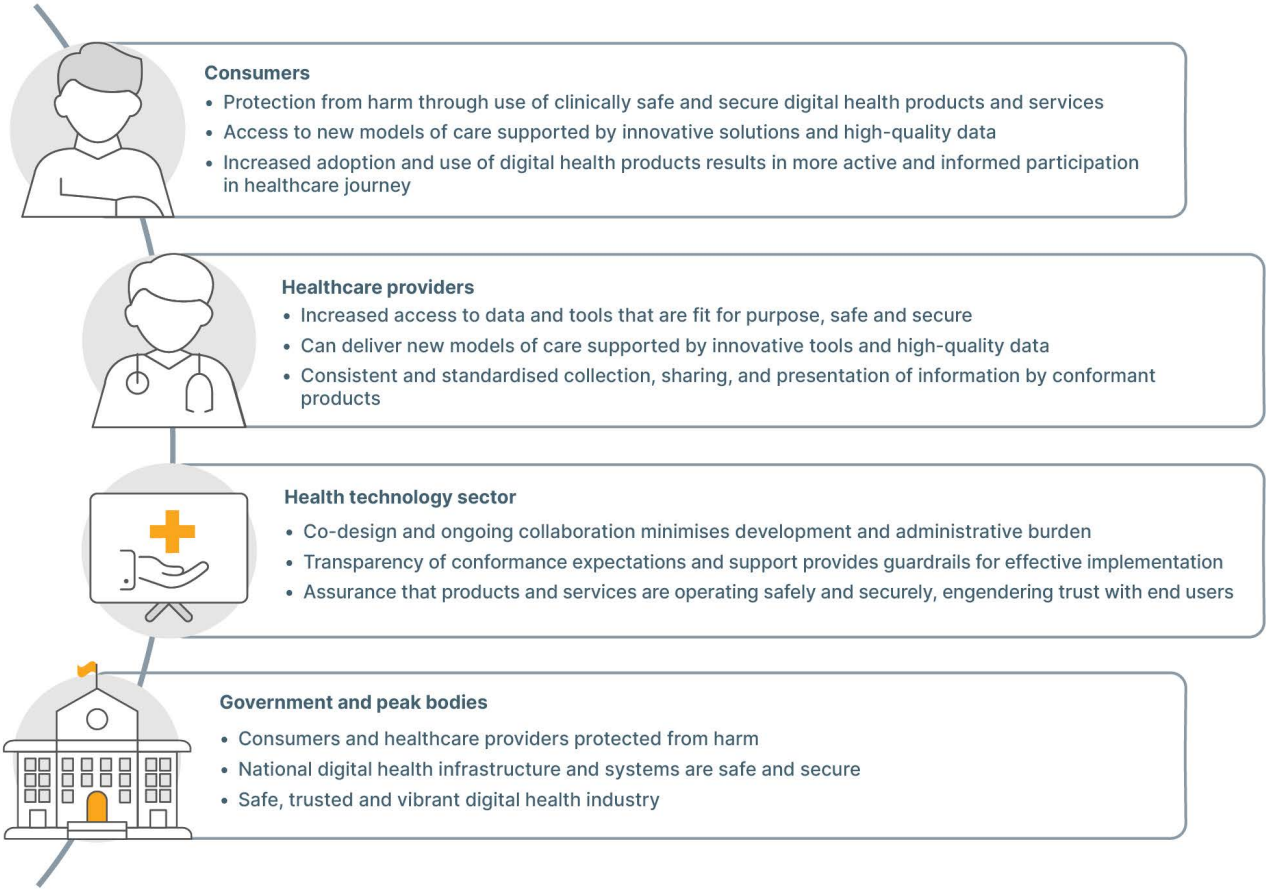


Benefits

The application of the Conformance Framework delivers benefits for all digital health consumers, participants and the digital health ecosystem by making them secure, safe and more interoperable.

However, benefits are typically realised beyond the context and scope of conformance services – at the point of delivery and use of conformant products and systems that enable digital health services and information to be available where and when they are needed. The framework will ensure clinically safe and secure digital systems in line with the Agency's National Digital Health Strategy and benefits. Figure 8 illustrates the benefits from the Agency's conformance and assurance services.

Figure 8: Benefits arising from application of the Conformance Framework



SECTION 3

Conformance and assurance approach

THIS SECTION INCLUDES:

- **Governance**
- **Conformance incident management**
- **Communication, engagement and collaboration**
- **Health technology developer conformance journey**

The fundamental components of the Agency's approach to conformance and assurance are:

- governance for conformance services
- conformance incident management
- effective communication, engagement and collaboration
- optimising the health technology developer conformance journey.

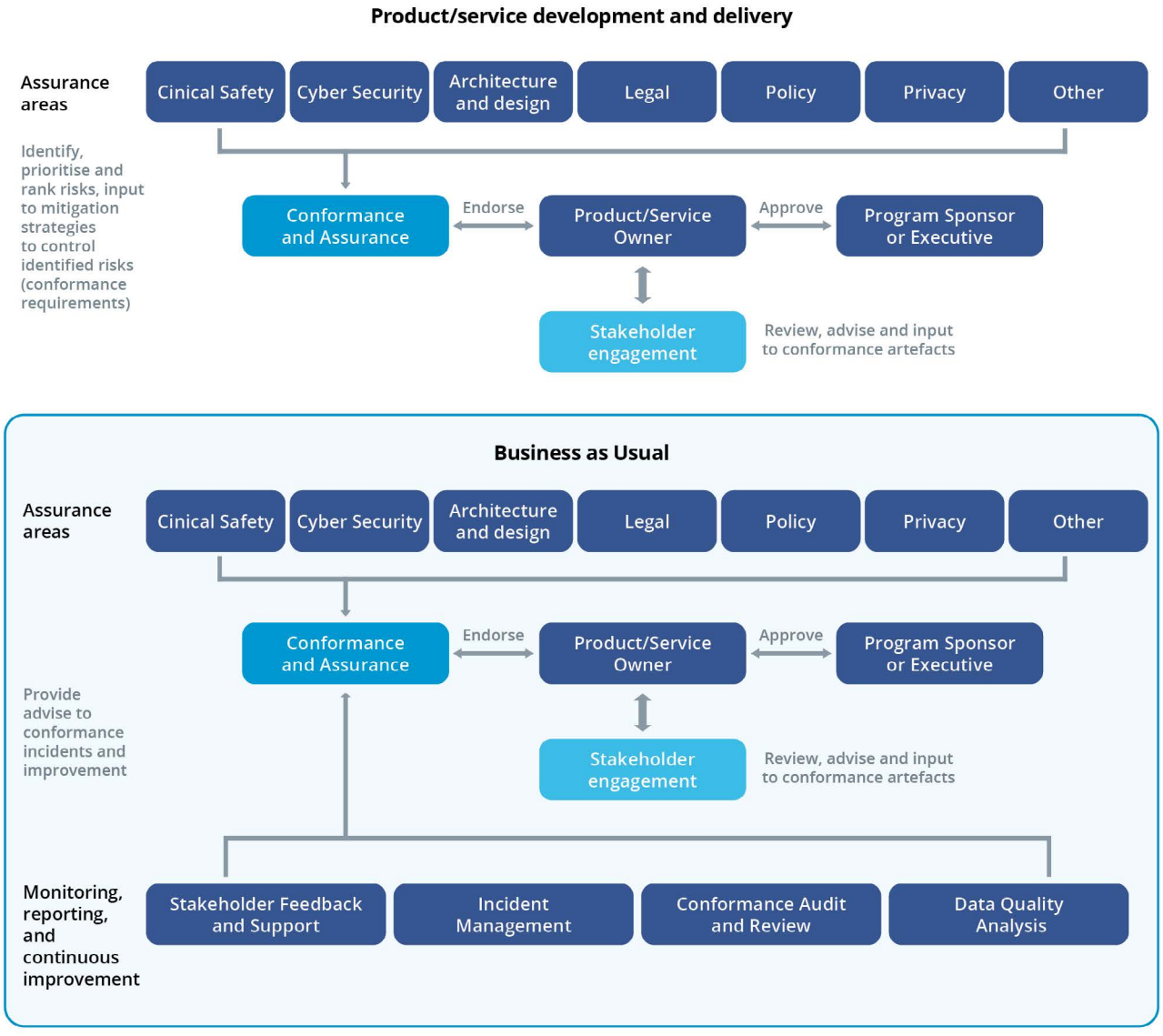
Governance

Strong governance underpins the conformance and assurance approach. It provides a formal suite of rules, processes, systems and assurance dimensions and defines the relationships and dependencies between them. Formalised governance ensures there is appropriate oversight, authority and accountability in the design and delivery of the Agency's conformance services. Governance is fit for purpose, so the structure, mechanisms and processes differ between the service design, service delivery and continuous improvement phases.

Conformance and assurance is delivered as a service; therefore the product or service owner has a level of shared accountability for the conformance assessment scheme. Products and services are typically linked to a program, so ultimate responsibility for decision-making rests with the program sponsor or executive. In the case of programs delivered by the Agency, this may be either a program board with delegated authority, the Agency Chief Executive Officer or the Agency Board as the Agency's accountable authority.

The Technical Standards Committee (TSC) plays a critical role in governing and providing oversight of the Conformance Framework. The TSC will ensure the integrity, strategic direction and guidance of the Conformance Framework, including any escalation matters or processes through the Director, Conformance and Assurance. The TSC ensures that the Conformance Framework incorporates best practice and standards for a robust governance and assurance approach (Figure 9).

Figure 9: Governance approach



The responsibility assignment matrix in Table 2 depicts the governance model and roles and responsibilities in the context of the key conformance service deliverables.

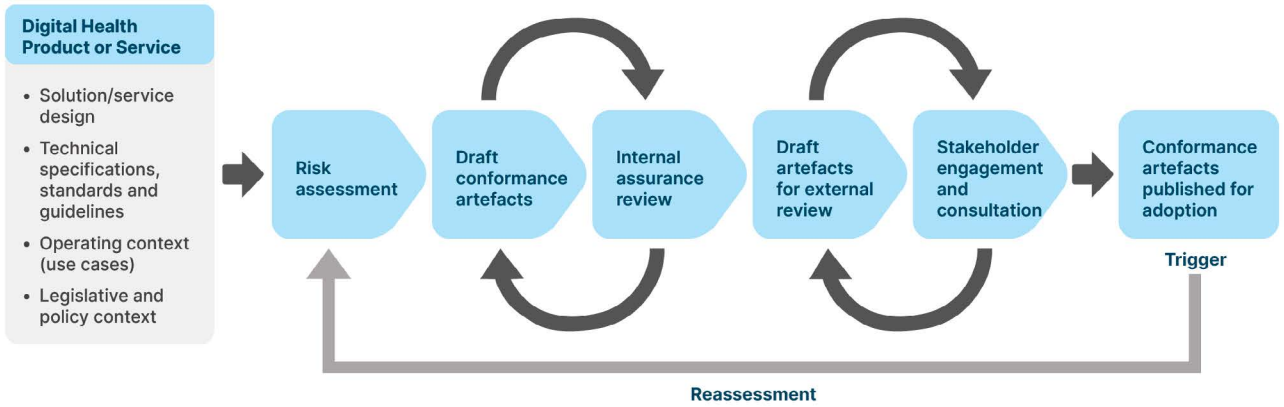
Table 2: Conformance and assurance service roles and responsibilities

Roles and responsibilities	Program sponsor or executive	Product/service owner	Agency assurance areas	Conformance and Assurance team	Conformance stakeholders
Risk assessment	Consulted	Consulted	Consulted	Responsible, Accountable	Consulted, Informed
Conformance requirements	Informed	Consulted	Consulted	Responsible, Accountable	Consulted, Informed
Conformance profile	Informed	Informed	Consulted	Responsible, Accountable	Consulted, Informed
Conformance test specifications	Informed	Consulted	Consulted	Responsible, Accountable	Consulted, Informed
Conformance assessment scheme	Accountable	(Accountable), Consulted	Consulted	Responsible	Consulted, Informed

Conformance stakeholders are engaged throughout the design and delivery of conformance services to varying degrees, dependent on their relationship to the conformance scheme. To uphold the principle of collaboration, working groups are typically established to provide input to the conformance co-design process. Working groups may comprise representatives from the health technology sector, consumer groups, peak bodies and governments. A time-limited or program-specific working group is considered a best practice mechanism to draw directly from stakeholder experiences and subject matter expertise in developing conformance artefacts. The Agency also draws on consultations with standards organisations to support international best practice where appropriate. Fostering productive engagement in this way also aims to build trust in the conformance process and serves to increase the likelihood of timely adoption of conformance profiles. It is also through this engagement that the Agency builds greater awareness of health technology developer roadmaps, capability, product development feasibility and any external influencing factors.

The Agency's internal assurance groups are key participants in the risk assessment process and iterative development cycle for all conformance artefacts. This iterative process, and its high-level inputs and phases, is depicted in Figure 10. Throughout this process, there are also several periods of internal conformance team peer review and approvals. This level of internal assurance ensures that only suitable, quality artefacts are released for engagement and consultation.

Figure 10: Conformance and assurance service design governance



Value of robust assurance

Each assurance dimensions introduces valuable perspective to the conformance risk assessment process and the development of conformance artefacts. Bringing together subject matter expertise across the various dimensions enables a holistic view of risk across the whole of a system or user journey, ensuring key dependencies are understood and appropriately considered. A summary of the assurance dimensions and an example of their focus in the risk assessment and review process is outlined in Table 3.

Table 3: Assurance dimension

Assurance dimension	Example frame of focus
Clinical safety	What is the risk of harm to consumers, healthcare providers and healthcare organisations in using this system or product? Will clinical workflows be impacted by this system or product design and operation, and to what extent? Are there any flow-on clinical impacts to be considered? Should clinical education or changes to clinical workflows be considered as alternatives, or used to support the intent of this system or product? Are the relevant standards applied appropriate?
Cyber security	What is the current and imminent threat landscape for the context in which the system or product will operate? Are proposed security controls feasible, appropriate and commensurate with the level of cyber security risk? Is existing cyber security maturity sufficient or does there need to be an overall maturity uplift to meet the requirements? Are the relevant standards applied appropriate?
Architecture and design	Are there any risks to the operation of underlying or dependent infrastructure and systems? Are there infrastructure or system constraints that would impact testing and conformance? Are the conformance requirements sufficiently technology-agnostic? Are there any impacts for existing design patterns or guidelines? Are the relevant standards applied appropriate?

Assurance dimension	Example frame of focus
Legal	Are proposed legal frameworks and instruments (e.g. declarations, deed polls, participation agreements) within the Agency's legislative powers? Is there appropriate apportion of liability and risk between entities connecting to national infrastructure? Are expectations placed on health technology developers lawful and appropriate? Do the requirements give rise to any legal or regulatory conflicts?
Policy	Is the proposal aligned with its respective legislative obligations and their intent? Is the proposal aligned with Agency and government policy and strategic direction, including the policies and future direction for national digital health initiatives? Is the proposal aligned with internal Agency policies that translate legislation into practice? Are the relevant standards applied appropriate?
Privacy	Are there real or potential privacy risks? Is the proposal compliant with the Australian Privacy Principles and privacy obligations in relevant Acts, for example Privacy Act 1988, Healthcare Identifiers Act 2010? Have privacy assurance activities been undertaken where applicable, that is, privacy impact assessment? Has the proposal considered other relevant privacy policies that may be applicable, including any program-specific policies and the Agency's Privacy Policy?
Other	Other subject matter experts may be engaged to address any new and emerging issues, for example the use of artificial intelligence. Are the relevant standards applied appropriate?

Risk management

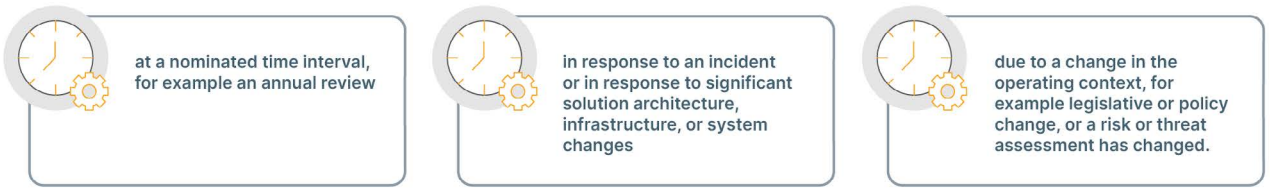
Effective risk management is a critical component of the Conformance Framework, ensuring the Agency can anticipate, mitigate and respond to risks. The Agency's internal Risk Management Framework uses a 4-staged approach to risk management, including identify, analyse, evaluate and treat risks. The Risk Management Framework helps the Agency prioritise activities, identify opportunities and create early warning mechanisms to manage risk. While using a robust conformance assurance approach, the Agency is able to ensure clinically safe, secure and interoperable digital systems based on a risk-based approach and continuous improvement.

Conformance artefact life cycle

Once a conformance service is operationalised and delivered, the monitoring, reporting and continuous improvement activities will result in a need to review and update various conformance artefacts over time. Timing to transition to new conformance artefacts shall afford all participating stakeholders reasonable time with which to achieve conformance and reasonable time for healthcare facilities to upgrade to any new version or conformance artefact. For example, a change in the cyber security threat landscape may trigger a revised risk assessment, resulting in changes to a number of cyber security related conformance requirements and test specifications across many conformance schemes.

The triggers for a review of a conformance artefact may include temporal, event-driven or context-driven triggers as per Figure 11.

Figure 11: Triggers for a conformance review



The above triggers for conformance review may result in the release of new or revised conformance artefacts. Table 4 describes the versioning approach to the release of conformance artefacts throughout their life cycle, and Figure 12 depicts this visually.

Table 4: Conformance artefact release versioning description

Release type	Description
Major	New initial artefact or a material update to an existing artefact, with several requirements added, modified or removed.
Minor	Material update to an existing artefact where there has been no trigger for a new major version and/or the scope of changes is not extensive. A minimal set of requirements may be added, modified or removed.
Maintenance	Non-material update to an existing artefact. Requirements may be added, modified or removed but the scope of changes is limited to enhanced language or structure of requirements for greater clarity, to remove ambiguity or to remove redundant requirements.

Figure 12: Conformance artefact release versioning (visual)

Managing conformance artefacts and upgrades

The management of conformance artefacts and any upgrades ensures that the most up-to-date standards and requirements are incorporated into conformance artefacts' continuous improvements through the conformance and assurance service design and delivery life cycle.

The Agency oversees the notification of new conformance artefacts to the health technology developer sector. This is usually done by formal letter and notifications, webinars and through direct consultations. This engagement aims to streamline the process for health technology developers by providing guidance and support on what has changed between versions to ensure stakeholders are aware of any additional or changed requirements.

Timing for these upgrades may depend on organisational circumstances and complexity of changes. The Agency ensures that transitioning timeframes are considered when managing conformance artefacts and the transition to new versions of conformance artefacts.

Health technology developers need to ensure adherence with current conformance artefacts to stay conformant. To do this they must ensure that they continue to upgrade their products to the most recent conformance artefact within a reasonable timeframe. Software is conformant as long as a conformance artefact has not sunset under the Agency's sunsetting arrangements.

Sunsetting conformance artefacts

Sunsetting is an important process involving the retirement of older conformance artefacts as new profiles become available. Sunsetting a conformance artefact results in a version becoming obsolete and no longer available for conformance assessment.

Health technology developers conformant under an obsolete version will cease to be able to transact. The Agency directly contacts health technology developers using older conformance profiles that are due to be sunset to support them with sufficient time to transition. This is to ensure a well-defined plan for upgrading to the latest version is in place for the health technology developer sector. The Agency manages sunsetting through ongoing collaboration with stakeholders and a version control process. Further information about managing conformance artefact versions and sunsetting arrangements will be included in each relevant conformance assessment scheme.

Conformance incident management

Incident management (non-conformance)

An incident management response may be triggered by the Agency as a result of non-conformance (an event trigger). Such incidents can arise, for example, from the interpretation of a requirement by a health technology developer or stakeholder during a conformance artefact's operation.

The Agency's incident management process ensures a responsive approach to any non-conformance matters that arise and will lead to development of more robust conformance artefacts for future release. The Agency works collaboratively across other government entities, health technology developers and stakeholders on incident management and could be involved in incidents that are non-conformance related but which identify a new gap or area to address in conformance artefacts.

Non-conformant products and conformance incidents

Non-conformant products are when software has been declared as conformant by the Agency, and during an identification, monitoring or other process the product does not comply or meet the necessary conformance requirements, standards and/or specifications in its relevant conformance artefacts. This non-conformant product may trigger a conformance incident and involve the Agency engaging relevant stakeholders to address the conformance incident.

Conformance incidents are when software or products no longer conform to one or more conformance requirement/s under a relevant conformance profile and may pose a clinical safety, security, privacy or other risk. Conformance incidents (non-conformances) can be detected through system monitoring, analysis or by direct reports to the Agency.

Table 5 illustrates the conformance incident management process within the Agency.

Table 5: Conformance incident management process

Step	Description
1. **Conformance incident reported/ identified**	Health technology developers who identify a non-conformance incident are required to report it to the Agency. The Agency has an incident management process that ensures the effective resolution of incidents under its remit and that identifies new risks, particularly with any new clinical safety risks. The Agency will undertake a consultation process with any stakeholders and health technology developers to understand the conformance incident.
2. **Impact assessment**	The Agency will use the outcomes from the consultation process to inform an impact assessment. The impact assessment will be undertaken in consultation with a variety of experts across the Agency, other government entities and stakeholders, with the health technology developer. The impact assessment may consider several options and potential outcomes, including weighing any potential risks such as letting the non-conformance continue while negotiating a resolution plan. The impact assessment may recommend the development of new conformance artefacts or requirements, or whether further education, retesting and or disconnection is required.
3. **Relevant stakeholders officially notified, and resolution plan negotiated and agreed**	The Agency will provide official notification to the relevant stakeholder or health technology developer following the consultation process and impact assessment. This official notification establishes a mutual understanding of the conformance incident, risks and impacts and will propose a course of action, including whether remediation steps are required.
4. **Relevant stakeholder provides evidence that the mitigation and actions remediate the conformance incident**	Once the non-conformance is addressed by the health technology developer, the Agency will require evidence, including any documentation or test reports, to prove the non-conformance incident has been rectified. The evidence required by the Agency may vary depending on the complexity of the conformance incident or product seeking conformance.
5. **Agency determines whether any gaps in conformance artefacts need to be addressed**	The Agency reviews conformance artefacts and determines whether further refinement or changes need to be made, that is, if additional conformance requirements are needed to address any gaps or future issues.
6. **Agency verifies software is remediated and requests release to production**	Following the verification of software, the Agency will then request a release to production, which may include a date for the production release. This release may inform part of the negotiation plan.
7. **If non-conformance is not remediated, the Agency may recommend removing the product from the register**	The Agency may recommend the removal of a non-conformant software product from a conformance register at its discretion if software does not meet conformance requirements. The Agency will work with health technology developers and stakeholders to support the regaining of conformance, which may include whether a recommendation for removal from a conformance register outweighs the risks associated with the non-conformant software product remaining on the register. This process ensures that any action taken is governed by a risk-based approach that maximises clinical and consumer safety.

Regaining conformance

Software conformance exists to ensure that software products and systems support good clinical governance and practice, mitigating both the likelihood and impact of adverse and unintended clinical outcomes. Adherence to conformance requirements is paramount to maintaining the integrity and efficacy of a range of digital systems across the health sector. The Agency will collaboratively work with stakeholders to ensure conformance is maintained. Where products have been identified as non-conformant, the Agency will work with stakeholders to regain conformance and remediate any risks to consumers including any potential ramifications of remaining non-conformant.

The Agency will undertake a consultation process with relevant governance groups, jurisdictions and other government agencies and entities to consider appropriate next steps and assist any health technology developer and stakeholders to regain conformance.

Communication, engagement and collaboration

Effective communication and engagement with the health technology developer community, and other conformance participants and stakeholders, is fundamental to the successful design and adoption of conformance schemes.

Fit-for-purpose engagement

The Agency utilises a range of channels to engage and collaborate when designing and delivering conformance services, including but not limited to:

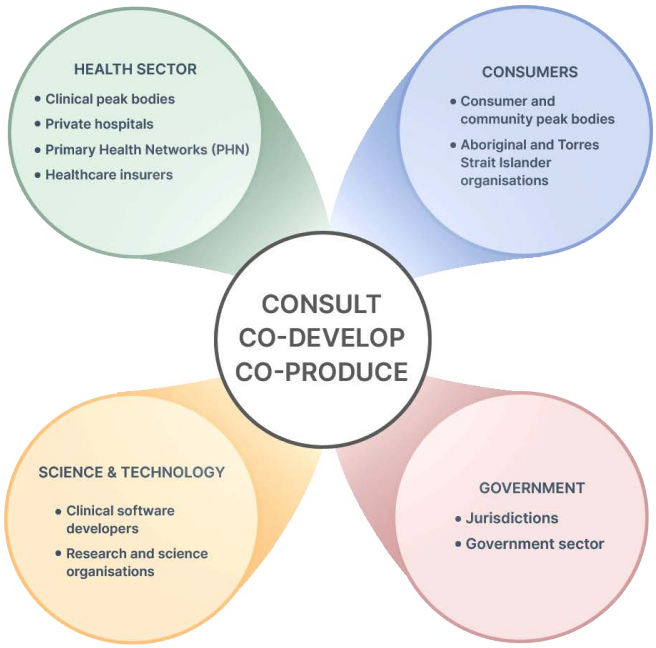
- Digital Health Developer Portal
- Help Centre (phone or email support)
- digital platforms (such as Collaborate and GovTeams)
- webinars and information sessions
- stakeholder working groups
- stakeholder forums and peak body or association meetings.

The channels and modes of communication, engagement and collaboration will vary dependent on the program or initiative and phase of delivery and will be selected based on both program and stakeholder needs and preferences.

In instances where conformance services are developed or delivered by other organisations such as the National Prescription Delivery Service or the Department of Health and Aged Care, the mode of engagement may be determined by that organisation in consultation with the Agency.

Irrespective of the modality, open communication that is tailored, targeted and timely underpins the collaborative co-design of conformance services. Co-design plays an important role in conformance and ensures that products, services or processes meet established standards and requirements. The Agency may undertake several co-design activities with stakeholders as part of the engagement process, including conducting workshops and collaborations on the development of conformance artefacts. Figure 13 Illustrates the Agency's strategic relationships and approach to fit-for-purpose engagement that involves a consult, co-develop and co-produce methodology.

Figure 13: Strategic relationships, Australian Digital Health Agency Corporate Plan 2023–2024



Iterative by default

Truly collaborative co-design is a process that benefits from cycles of review and refinement. Adopting an iterative approach to consultation ensures that there are several opportunities for stakeholders to provide input to the design of conformance services, and to adapt and evolve more readily in response to feedback or changes in context, requirements and needs.

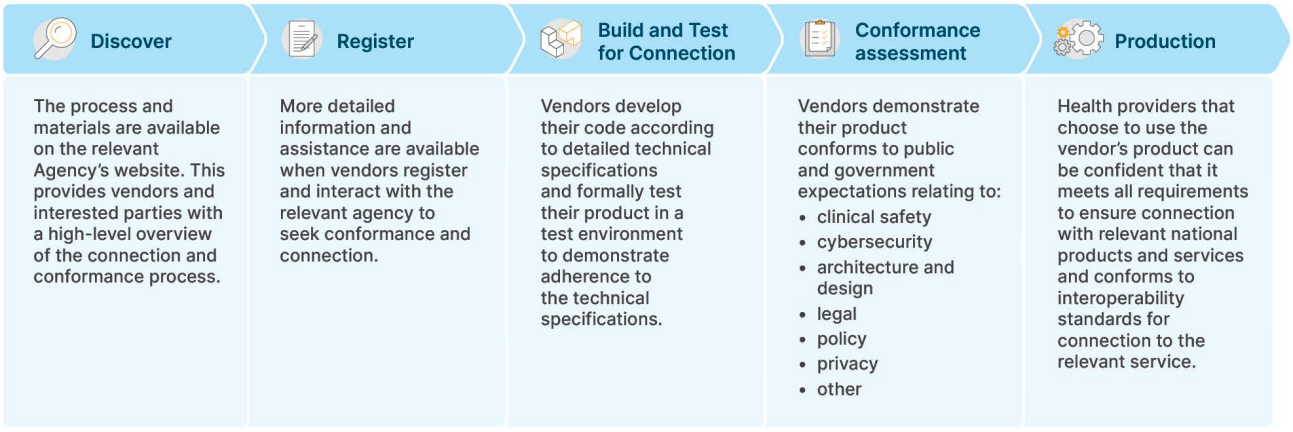
Conformance schemes are very rarely 'set and forget'; therefore, the ongoing delivery and continuous improvement of conformance schemes is also an iterative process by nature. This is most evident in the life cycle of published conformance artefacts, with multiple versions existing throughout the life of a conformance scheme and often multiple versions of artefacts existing concurrently.

Health technology developer conformance journey

The health technology developer journey is co-designed with the sector to optimise and streamline the process for all participants, to encourage conformance. Figure 14 depicts a common health technology developer journey, inclusive of the high-level steps in the end-to-end conformance process.

Health technology developers may be supported throughout their conformance journey by a number of Agency resources and people, including the Digital Health Developer Portal and Customer Care, Partnerships and Connections team. Health technology developers may also interact with third-party service providers or system operators that operate or maintain infrastructure or products on behalf of the Agency and its stakeholders, including the National Infrastructure Operator and Services Australia.

Figure 14: Typical health technology developer journey



Conformance prerequisites and prior recognition

In some cases, digital health products are required to achieve conformance for connection to foundational or dependent services prior to becoming conformant for their target service.

For example, software that is intended to interact with My Health Record will also be required to use the Healthcare Identifiers (HI) Service. My Health Record and the HI Service each have a conformance assessment scheme that is unique to the service. Health technology developers will need to implement HI Service functionality for a product and complete a conformance assessment prior to being able to complete conformance testing for My Health Record.

For products that use middleware or common adaptors/integrators for service connections, conformance testing and assessment for multiple products can often be accelerated. In these cases, prerequisites may be satisfied through use of these existing conformant products. If multiple conformance assessment schemes have the same prerequisites, provided all of the relevant requirements specific to the product use case are met, prior conformance or use of existing conformant products will be recognised.

As an example, if a product that is conformant for both the HI Service and My Health Record intends to participate in electronic prescribing, then prior conformance with the relevant, related use cases for the HI Service may be recognised, satisfying the prerequisite for the electronic prescribing conformance assessment scheme.

As the digital health ecosystem evolves, there may be a range of conformance prerequisites applicable for new or existing conformance assessment schemes. The Agency will inform health technology developers of any prerequisites and any mechanisms that may exist to have prior conformance recognised, through the conformance assessment scheme documentation and supporting material published by the Agency.

Conformance registers

Product and service owners maintain and own conformance registers based on different agreements and legislative instruments for each conformance service they operate. The conformance registers are published by product and service owners on their relevant websites and are available to health technology developers, healthcare providers and other interested stakeholders. Registers are updated when products are declared conformant and/or are granted access to production environments for national digital health infrastructure.

Inclusion on a conformance register is voluntary, and health technology developers can elect to not have their details published. When a software product version is listed on a conformance register, software may continue to be upgraded and/or changed to a new version. A new version of the software will not be listed on a conformance register until a health technology developer has validated the new version with the Agency through a formal conformance assessment process.

Where a health technology developer offers multiple versions of their software that implement conformance profiles, each software version will be listed in the relevant conformance register as a separate entry.

The public registers are populated from information gathered during the health technology developer conformance journey with the Agency. The Agency maintains internal registers that store information about specific product functionality and conformance use cases that have been implemented.

Short forms

Acronym	Description
CTS	Conformance Test Specifications
HI	Healthcare Identifier
TSC	Technical Standards Committee

Glossary

Term	Meaning
assurance	The level of confidence that software functions as intended and is free of vulnerabilities, either intentionally or unintentionally designed or inserted as part of the software throughout the life cycle.
business as usual	The ongoing operational phase after product delivery for the life cycle of the product.
business use case	Business use cases are scenarios developed to test the conformance requirements in the conformance profile. The use cases typically describe the type of software/system implementation or the context in which it is used.
conformance	A determination (by testing) of the adherence of an implementation to a specification or standard.
conformance assessment	Using a documented procedure to test that software adheres to a standard or specification by determining its characteristics.
conformance assessment scheme	The approach to develop and assess the conformance of software against the conformance requirements.
conformance profile	Identifies risks, outlines mitigation strategies to control identified risks and describes desired software behaviours.
conformance requirement	The software functionality or behaviour to be implemented; it will be either mandatory, conditional or recommended. A conformance profile comprises a number of conformance requirements.
conformance test specifications	The tests to be undertaken and passed to become conformant. The test specification contains the conformance test cases that are aligned to the conformance profile use cases, and in some cases include or reference the test data that must be used to execute the test cases.
conformant	The health technology developer software behaves in accordance with the desired software behaviours expected per the conformance profile and artefacts.
consumers	Any person in receipt of services from the healthcare system.
data quality	Monitors and measures quality dimensions of completeness, conformance, information model variations, plausibility and timeliness.
evidence verification	The health technology developer executes formal self-assessment and submits evidence of successful test completion to the Agency.
exemption	The health technology developer seeks not to have to undertake conformance activities for part or all elements of their software.
health technology developer	An organisation that develops a software product, or a provider of digital health services.
modular approach	An approach in conformance and assurance that separates conformance requirements into different profiles based on elements such as data sensitivity or information domains. Emerging trends or changes could result in updates to a 'modular part' without impacting the other various parts of the conformance assessment scheme.
non-conformant	Where a health technology developer's software or product is not or no longer conformant to one or more conformance requirement/s under a relevant conformance profile and does not meet the definition of conformance under section 2.2.1.
observed self-assessment	The Agency or third-party partner will observe the health technology developer testing their software by using the test cases published by the Agency (if available).
participant/s	Individuals or organisations involved in conformance activities including but not limited to risk assessments, or other health ecosystem activities where conformance is applicable.

Term	Meaning
product owner	An ongoing functional role as a stakeholder and/or project team member to deliver a digital health product/system and maintain product oversight (including conformance and assurance) in the business-as-usual phase
self-declaration	The health technology developer completes an independent self-assessment against the conformance requirements and completes and submits a Declaration of Conformity relevant to the program of work.
standard	A document that sets out specifications, procedures and guidelines that aim to ensure that the products, services and systems listed on the Standards Catalogue are safe, consistent and reliable.
sunsetting	The date on which an artefact version becomes obsolete and is no longer a supported version.
technical specifications	A detailed and comprehensive document that describes all technical procedures related to product development.
third-party assessment	Testing is conducted by test laboratories or qualified software testing organisations.
working group	A time-limited functional group that provides input and advice on conformance artefacts.

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Australian Government

Australian Digital Health Agency