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1 Executive summary

1.1 Why do we have a clinical governance framework?

Digital health services and technologies are changing the way in which healthcare is provided and experienced worldwide. This change brings Australia significant health system efficiencies and clinical benefits, including improvements in the management of clinical risk and patient safety. Conversely, constant vigilance of our broader digital health system is required – supported through a safety culture and governance structures – to maintain oversight and management of unique safety and quality challenges brought about through digital health. These challenges reach beyond technology to the whole-of-system impacts created through digital enablement.

While the Australian Digital Health Agency is not a direct provider of clinical care to the Australian community or a regulator of digital health, it has a legislated responsibility to ensure the safety and quality development of the products, service and infrastructure it manages.

The Public Governance Performance and Accountability Rule (PGPA Rule) [1] under which the Agency has been established, specifically acknowledges that a core function of the Agency is to “Develop, implement and operate comprehensive and effective clinical governance, using a whole of system approach, to ensure clinical safety in the delivery of the national digital health work program”.

In recognition of the national leadership the Agency has been afforded, a comprehensive clinical governance framework is required that focuses on the end-user experience, effectively manages risk, promotes a shared responsibility for safe and high-quality care, and enables continuous improvement.

1.2 Clinical governance principles

This Clinical Governance Framework outlines 11 guiding principles that have been tailored to the context of the role and accountabilities of the Agency, its work activities and the receivers and providers of health care it supports. The principles are not hierarchical and are interconnected, as illustrated in Figure 1 below. These principles focus on the consumer experience as central. They aim to foster a safety culture for the organisation and embed this culture in the broader corporate and delivery governance structures of the Agency.
1.3 The framework at a glance

The framework describes the requirement for people, systems, structures and processes that support the development of safe and high-quality products, services and infrastructure. It focusses on working together with co-production and user-centred design approaches throughout the development lifecycle to deliver the organisations work with high standards of safety and quality.

Key functional components of the Agency’s clinical governance systems and processes are described within the framework and required for its successful implementation. These include:

- The Agency’s clinical governance principles
- Committee structures relating to quality and safety
- Policies and procedures relating to quality and safety
- Risk management processes to guide the development of products and services
- Event and incident management and external assurance processes
- Processes to support a culture of organisational safety
• Performance monitoring and reporting for the Agency relating to quality and safety.


2 Purpose

This document defines the framework for the Agency. The purpose of the framework is to provide guidance for the Agency in its endeavours to continuously improve the quality and safety of its products and services and create an environment in which there is transparent responsibility and accountability for maintaining and safeguarding high standards of safety and quality in the delivery of these. Application of the framework will ensure that, while achieving strategic priorities, management of safety and quality is paramount.

This framework places in context the role of clinical governance, where a multiplicity of relationships to healthcare organisations, providers and technology impacts the wellbeing, clinical risk and experience of consumers. It aims to support the Agency’s whole-of-system approach to clinical governance in the delivery of the national digital health work plan, including the operation of the My Health Record system.

Under the PGPA Rule 2016 [1] and the My Health Records Act 2012 [2], the Agency has a number of specific responsibilities as the System Operator of the My Health Record system. The Agency does not have the power or authority to regulate digital health activity, but it may in accordance with its functions set out in section 9 of the PGPA Rule:

• Coordinate and provide input into the ongoing development of the National Digital Health Strategy;
• Implement aspects of the National Digital Health Strategy that are directed by the Australian Health Ministers’ Advisory Council (AHMAC);
• Develop, implement, manage, operate and continuously innovate and improve specifications, standards, systems and services in relation to digital health, consistently with the national digital health work program;
• Develop, implement and operate comprehensive and effective clinical governance, using a whole of system approach, to ensure clinical safety in the delivery of the national digital health work program;
• Develop, monitor and manage specifications and standards to maximise effective interoperability of public and private sector digital health systems;
• Develop and implement compliance approaches in relation to the adoption of agreed specifications and standards relating to digital health;
• Liaise and cooperate with local and international peak bodies on matters relating to digital health;
• Undertake other functions as are conferred on the Agency by the PGPA Rule 2016 [1] or by any other law of the Commonwealth;
• Anything incidental to or conducive to the performance of any of the above functions.

This framework takes relevant components of these specific responsibilities into consideration.
3 Digital health quality and safety leadership in Australia

The Australian healthcare system is a complex network of multiple system participants, and associated interdependencies. This complexity extends across national, state and territory jurisdictions; primary, secondary and tertiary care. The maturity and capability levels of healthcare participants across the system in both service delivery models and digital health differs significantly.

The expectations placed on the healthcare system are also expanding and evolving as technology becomes more embedded into almost every facet of daily life for Australians. Digital innovation is revolutionising the way information is accessed, communicated and used. It provides Australians with new ways to connect to each other and is changing how they understand and manage different aspects of their own life, including their health and wellbeing. Digital solutions are fundamentally transforming the healthcare system and the very way healthcare is provided.

Alongside the Agency, there are several organisations who have a leading role in digital health quality and safety guidance. Their clinical governance systems and approaches are an important consideration for the Agency in the ongoing development and application of the framework.

3.1 Australian Commission on Safety and Quality in Health Care

The Australian Commission on Safety and Quality in Health Care (ACSQHC) is an Australian Government agency established under the National Health Reform Act (2011). The ACSQHC is jointly funded by all governments on a cost sharing basis. The ACSQHC’s annual program of work is developed in consultation with the Australian, state and territory Health ministers.

The ACSQHC recognises the importance and the potential for digital health to facilitate safe, high quality patient-centred care. The ACSQHC’s strategy and work plans identifies digital health as one of the top five areas under the ‘Patient Safety’ Strategic Priority. The ACSQHC and the Agency collaborate on a range of digital health patient safety projects. This partnership is crucial to the Agency’s Clinical Governance Framework (this document) to achieve the development of high quality and safe products.

3.2 Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA) is a regulatory entity under the Department of Health, which is responsible for protecting the Australian community through the regulation of therapeutic goods.

A product is considered by the TGA to be therapeutic when its intended use is for a range of purposes, including the; prevention, diagnosis, curing or alleviation of a disease, ailment, defect or injury. Products under this definition include medical devices and associated software [3].

3.3 State and territory jurisdictions

The state and territory jurisdictions oversee complex and diverse healthcare systems and services. The associated information communication technology (ICT) systems that are utilised across these services varies significantly in their scope and reach between jurisdictions.
The state and territory jurisdictions each maintain clinical governance responsibility and accountability over their own respective services and the locally owned and administered ICT services that articulate to the Agency’s products.

3.4 Key clinical peak bodies
Consultation and engagement with peak bodies, Australian and international, is necessary to better understand the challenges and needs of healthcare providers and to gain support for the participation and adoption of the Agency’s digital health products and services.

The partnerships that the Agency has developed with key clinical peak bodies has resulted in aligned communications and further engagement with clinicians regarding digital health. This has further supported the uptake and adoption of the Agency’s digital health products and services.
4 The role of the Agency

4.1 Defining clinical governance

The ACSQHC is recognised as the leading national authority to provide advice on safety and quality in healthcare. They define clinical governance as:

‘A system through which organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care. This is achieved by creating an environment in which there is transparent responsibility and accountability for maintaining standards and by allowing excellence in clinical care to flourish.’

This definition is accepted by the Agency as the foundation for this framework, recognising that clinical risk associated with its products and services must be effectively managed.

4.2 Clinical risks in digital health

The framework recognises that, while digital enablement provides the opportunity for significant safety benefits, the possibility exists for several unintended clinical risks to emerge. Some of these clinical risks are well understood and are inherited from paper-based healthcare record keeping complexity and others are new, sometimes unexpected and require specific approaches to risk control.

Summarised below are the key clinical risks identified through prospective analysis of digital health products and infrastructure. These risks represent themes seen in incidents reported to date and through My Health Record clinical safety reviews undertaken by the ACSQHC:

- **Misidentification** – identity management errors in source systems and workflows that in turn lead to mismatches of individual healthcare identifiers (IHIs) with clinical information. My Health Record system design requires the IHI as the unique key for uploading information to the My Health Record system.

- **Loss of information** – information may not be uploaded successfully because of failing technical validations.

- **Incorrect information** – the information uploaded to the digital health record from the source system may be incorrect or ambiguous.

- **Human error** – clinical staff may use systems in good faith, however, inadvertently not detect that they are contributing to inaccuracies in clinical content.

- **Expired authentication certificates** – which prevents the uploading of clinical documents to a patient’s My Health Record.

4.3 System Operator responsibilities for maintaining My Health Record accuracy

As outlined above, key clinical risks relate to information that is missing, correct but poorly presented, or incorrect. As the System Operator, the Agency is not responsible for the clinical content, including content uploaded to the My Health Record system. Under the My Health Records Act, the Agency and healthcare participants must be responsive to clinical risks associated with information, including requests for changes to clinical records by consumers to appropriately reflect their views.
Several features enable consumer control of the My Health Record and this reflects the intention of the My Health Records Act to maximise the ability for a consumer to ensure accuracy and currency of information of their own record. These features include the ability to ‘remove information from view’ should they believe the information is incorrect.

To support consumer (and healthcare provider) use and participation in the My Health Record system, a help line operates for consumers to report incorrect information in their My Health Record. All reported system incidents, including clinical events and incidents, are immediately escalated to the System Operator in accordance with the Agency’s incident management frameworks and procedures (see Section 6.3.3).

4.4 Application of the framework to Agency’s strategic priorities

The Agency has developed strategic priorities to focus its activities and reflect the commitment to develop clinically safe and high quality national infrastructure products and services, and the digital enablement of system participants. The associated priority areas for delivery to 2022 are detailed in Figure 2 below.

<table>
<thead>
<tr>
<th>MY HEALTH RECORD</th>
<th>Health information that is available whenever and wherever it is needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>SECURE MESSAGING</td>
<td>Health information that can be exchanged securely</td>
</tr>
<tr>
<td>INTEROPERABILITY AND DATA QUALITY</td>
<td>High-quality data with a commonly understood meaning that can be used with confidence</td>
</tr>
<tr>
<td>MEDICATION SAFETY</td>
<td>Better availability &amp; access to prescriptions &amp; medicines information</td>
</tr>
<tr>
<td>ENHANCE MODELS OF CARE</td>
<td>Digitally-enabled models of care that drive improved accessibility, quality, safety and efficiency</td>
</tr>
<tr>
<td>WORKFORCE EDUCATION</td>
<td>A workforce confidently using digital health technologies to deliver health and care</td>
</tr>
<tr>
<td>DRIVE INNOVATION</td>
<td>A thriving digital health industry delivering world-class innovation</td>
</tr>
</tbody>
</table>

*Figure 2 - Agency priority areas for delivery to 2022*

4.5 Relationship to other Agency frameworks

4.5.1 Enterprise risk management

The Agency has an established risk management strategy, framework and policy (RMSFP). Collectively, this set of policies, processes and structures through which the Agency manages enterprise risk, can be referred to as the Agency Risk Management Framework [4]. The Risk Management Framework represents a systematic and comprehensive process the Agency has put in place to ensure that we manage risks effectively, and that risk management contributes to improved Agency services and outcomes, achieving the objectives we are tasked with delivering. Key aspects of the Risk Management Framework are outlined in Figure 3 [4]
Clinical risks are referred to as ‘specialist risks’ for reporting. The management and maintenance of the Agency’s Strategic Risk Register is performed by the Governance Services Team. The Executive Leadership Team are responsible for advising, monitoring and action implementation of the strategic risks.

Applying the principle of co-production to the Agency’s systems and services may result in a requirement to understand shared liabilities, relating to its inclusive nature and emphasis on partnerships. Such shared risk assessments will be conducted by Agency officials responsible for identifying and investigating potential shared risks and take account the zero appetite for clinical safety risk.

The Agency has no appetite for taking risks associated with activities that may impact clinical safety as outlined by the Agency Board. A full description can be found in the Agency Risk Management Strategy, Framework and Policy (RMSFP) and Risk Management Toolkit [5].

4.5.2 Stakeholder Engagement Framework

This framework, as depicted in Figure 4, supports the delivery of the Stakeholder Engagement Framework. This framework together with the Service Delivery and Design Framework outline the commitment to collaborating through co-design with key stakeholders.
4.5.3 Service Delivery and Design Framework

The Agency developed the Service Delivery and Design Framework to have consistency and best practice methods used in design and delivery of its services and products. The framework implements the principles of Collaborative. Evidence-based. Iterative. Transparent. Consistent [5].

4.5.4 My Health Record Incident Management Framework

The Incident Management Framework and supporting Standard Operating Procedures describe the Agency’s process for managing My Health Record events and incidents, which may or may not have an impact on the care of an individual. The Incident Management Framework sets out the roles, responsibilities, and processes for dealing with unplanned interruptions to, or a reduction in the quality of, the My Health Record system and any associated systems and services.

Event and incident management focuses on assuring clinical safety and restoring normal service operation as quickly as possible and minimising the adverse impact on business operations, while maintaining the highest possible levels of service quality and availability. The specific approach to clinically significant events and incidents is detailed in Section 6.3.3.
5 Key clinical governance principles

The following guiding principles, in Figure 5, for this framework have been co-designed by the Agency’s executive and senior leadership teams, clinical reference leads, and through consultation with the ACSQHC. The guiding principles have been tailored to the context of the role and accountabilities of the Agency, its work activities and its participants.

5.1 Focus on the consumer experience

The ACSQHC has identified, in their corporate strategy and plans [6], the consumer experience as being critical to improving quality across the healthcare system. It requires an understanding of what the dimensions of quality are for consumers within the digital health context. This
framework incorporates structures and mechanisms that place the consumer experience at the forefront.

5.2 Alignment with the Agency’s strategic priorities
This framework provides the required rigour for the Agency to achieve the strategic priorities, while managing the safety and quality of its products and services. Practically, this will mean working closely with product, program and project governance underpinning work plans, and embedding structured reporting and escalations to specific clinical governance committees when appropriate.

5.3 Culture of safety and quality improvement
Organisational culture guides how employees think and act in their roles, and how the organisation and its people interact and build relationships with its internal and external participants. Culture is widely recognised as being a core building block to an effective and successful organisation. This is reinforced by the Australian Public Service Commission guide ‘Strengthening a values-based culture: A plan for integrating the APS Values into the way we work’ [7].

The organisational values are exemplified in the interactions of all Agency employees as ambassadors of digital health, internally and with external participants. The framework supports the Agency’s values and culture, embedding clinical safety and quality improvement within the organisation’s core processes. While policies, processes, procedures and systems define the optimal pathway for the correct treatment of risk, culture plays a pivotal role in how a risk is managed. The risk culture chain in Figure 6 illustrates the importance of behaviours to the day to day treatment of risks.

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**Figure 6 - Risk culture chain**
5.4 Effective leadership and accountability

Good clinical governance is founded on effective leadership and defined roles of responsibility and accountability. The key elements of effective leadership and accountability are:

- Clear articulation of responsibilities and accountabilities, promoting ownership throughout the organisation.
- Leaders and owners being proactive in their roles to drive the clinical safety and quality agenda, that is cascaded throughout the organisation.
- Roles and responsibilities for clinical governance processes and systems are clearly documented, managed and accessible to support staff understanding of the appropriate management of identified clinical risks, events and incidents.
- The skills base of people in leadership roles must be of the required calibre to undertake the scope of their clinical governance related responsibilities.

5.5 Transparent external assurance

External assurance validates the effectiveness of the Agency’s systems for safety and quality by providing objective review and evaluation processes. Transparent independent expert advice provides the confidence to the Agency’s Chief Executive Officer that safety and quality is upheld in the development, implementation and operation of its products and services.

The regular conduct of transparent external assurance by an independent body provides an objective evaluation of clinical governance.

5.6 Integrated and responsive risk, event and incident management

Proactive, transparent and responsive risk, event and incident monitoring and management processes are essential for the Agency to consistently manage the safety and quality of its products and services.

5.7 Governance embedded into core business processes

A process or system that sits outside of core organisational activities is susceptible to being used by exception only. Processes that are used by exception lose their effectiveness in delivering the intended benefits and outcomes.

5.8 Evidence-based models of care

For digital health to improve health outcomes for the Australian population, it must support evidence-based models of care. The Agency’s digital health products and services are developed to be of high quality, clinically effective and usable, and supported by systems to protect the security and integrity of the data. The Agency’s research and evaluation program ensures that product and service delivery and development occur with consideration of high quality evidence. The Agency also engages members of the clinical community, embedding them into co-production project teams, to support the development of products and services that are evidence based.

5.9 High quality data security and privacy

Consumers want to be empowered to control their health information, including the access and integrity of data. The Agency is committed to developing secure products and services that support the privacy of its users. Furthermore, there are obligations under the Privacy Act (1988) and the My Health Records Act [2] for the Agency to maintain compliance with the national and local privacy legislation for the development and delivery of its products and services.
Data security and privacy extends beyond the legal domain and directly impacts the trust in which the consumers and participants place in digital health products and services. Additionally, cybersecurity is a major focus of the Australian Commonwealth Government and is demonstrated by the establishment of the Cybersecurity Strategy [8] for protecting Australians from threats and attacks within the cyber domain.

5.10 Frameworks, policies and processes are built to last and fit for purpose

The Agency operates in an environment of rapid innovation and change. To remain effective and sustainable in this dynamic environment, the framework has supporting policies, processes and procedures that are robust and tailored to the environment in which it operates.

The framework’s structures and systems are appropriately flexible to support changes in ways of working, new digital innovations in the market, the growing needs of users, and changes in policy and legislation. All Agency frameworks include a requirement for regular review and update to ensure currency and ongoing effectiveness.

5.11 Co-production, with a user-centred design approach

Co-production is defined as the process of soliciting user contribution into the development and provision of products and services, resulting in outcomes that better meet user needs (Realpe and Wallace [9]).

Developing and delivering digital products without a complete understanding of the end user’s experience may result in a product that is not usable, is potentially unsafe and ineffective. The Agency uses a co-production and user-centred design approach throughout its operations and the product development lifecycle of its products and services. This is demonstrated through the integration of nominated consumer and clinical representatives into the Agency’s project and program teams.
6 Clinical governance in action

The clinical governance principles do not stand alone in achieving the objectives of the framework. Clinical governance must be observed ‘in action’, be measurable and contribute to the organisation’s performance.

6.1 Committee structures and workforce capability

6.1.1 The Agency Board

The Agency Board includes experts from multiple fields, including but not limited to: safety and quality, clinical governance, delivery and patient health advocacy. This Board is accountable for the performance of the Agency’s objectives and uses the following integrated committee structures to support clinical governance in operations and key decision making (Figure 7) inside the highlighted area in yellow.

![Agency Governance Structure supporting the Framework](image-url)

Figure 7 - Governance structure that supports the framework
Effective governance structures reflect a pathway for the reporting, monitoring and tracking of clinical quality and safety issues across the Agency’s priority areas and work plans. Clinical quality and safety issues are identified, monitored and reported by each of the respective committees to the Executive or Board level of the organisation.

6.1.2 Chief Executive and Leadership Team
The Agency Chief Executive Officer (CEO) with the Leadership Team has the overall responsibility for the implementation of the Board’s strategy and policy. This requires the development and maintenance of effective processes and the allocation of sufficient resources to maintain strong clinical governance processes.

6.1.3 External Assurance Committee
The External Assurance Committee, chaired by the ACSQHC, reports directly to the Agency CEO. It was established to provide independent, expert advice on clinical safety, quality and governance for the Agency.

6.1.4 Clinical Governance Committee
The Clinical Governance Committee is the Agency’s primary operational mechanism that drives and oversees the application of this framework throughout the organisation.

This committee functions as the peak operational level committee receiving escalated clinical risks, events and incidents. Responsibility is delegated for the implementation of action plans to manage identified clinical risks and quality issues.

6.1.5 Clinical Governance Branch
The Clinical Governance Branch is a part of the Clinical Advisory, Safety & Quality Division of the Agency.

This branch leads and manages the application of the clinical risk management lifecycle to Agency products and services, including event and incident management.

6.1.6 Clinical reference leads
The clinical reference leads are the Agency’s clinical expert panel providing rapid-response clinical advice. These clinicians are also embedded into product development project teams as part of the Agency’s co-production approach.

They provide on-hand clinical advice and broker relationships with key external clinical participant groups and peak bodies for further advice and input, as required.

6.1.7 Summary of committees and groups
The table below provides a summary of the Agency committee and group structures and memberships related to clinical governance activities.
### Table 1 - Agency committees and groups - related to the framework

<table>
<thead>
<tr>
<th>Name of committee/group</th>
<th>Summary of function/role</th>
<th>Description of membership</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical and Technical Advisory Committee</td>
<td>Standing committee providing advice to the Board about delivery of digital health in clinical care</td>
<td>Representation from multiple health and information communication technology sectors</td>
</tr>
<tr>
<td>Jurisdictional Advisory Committee</td>
<td>Standing committee providing advice to the Board regarding interoperability and national consistency in relation to digital health</td>
<td>Nominated representatives from state and territory jurisdictions</td>
</tr>
<tr>
<td>Consumer Advisory Committee</td>
<td>Standing committee providing advice to the Board on communication and engagement</td>
<td>Skills-based board with representation from multiple health and people groups</td>
</tr>
<tr>
<td>Privacy and Security Advisory Committee</td>
<td>Standing committee providing advice to the Board on legal issues regarding data privacy and security</td>
<td>Skills-based board with representation from medico-legal backgrounds</td>
</tr>
<tr>
<td>Audit and Risk Committee</td>
<td>Non-standing committee providing advice to the Board on organisational compliance with performance and financial requirements</td>
<td>Representatives from the Australian National Audit Office and with auditing backgrounds</td>
</tr>
<tr>
<td>External Assurance Committee</td>
<td>Independent body providing assurance over the Agency’s Clinical Governance Framework and performance</td>
<td>Executives from the ACSQHC, Commonwealth Department of Health, AHPRA Chief Executive Officer, and other key opinion leaders</td>
</tr>
<tr>
<td>Clinical Governance Committee</td>
<td>Peak operational level management committee operationalising the safety, quality and clinical governance aspects of the organisation</td>
<td>Agency executive general managers and relevant general managers with clinical background and expertise</td>
</tr>
<tr>
<td>Portfolio Management Committee</td>
<td>Management of programs across the Agency</td>
<td>Relevant executive general managers, general managers and representation from the Clinical Governance Committee</td>
</tr>
<tr>
<td>Program Delivery Committee</td>
<td>Oversight of My Health Record expansion projects</td>
<td>Agency executive general managers and relevant general managers</td>
</tr>
<tr>
<td>Risk Management Forum</td>
<td>Management forum for the identification and escalating of identified Clinical Risks regarding the Agency’s products, services and operational activities</td>
<td>Agency general managers and relevant directors</td>
</tr>
<tr>
<td>Clinical Reference Leads</td>
<td>Provides clinical advice to the Agency supporting product development and operations</td>
<td>Practising clinicians from multiple health fields</td>
</tr>
</tbody>
</table>

### 6.1.8 Key leadership roles in the application of this framework

Recognising the critical impact of specific roles in the organisation to ‘live’ the principles of clinical governance outlined in the framework, the scope of these roles is outlined in the table below.
Table 2 - Leadership roles involved in the application of this framework

<table>
<thead>
<tr>
<th>Position title</th>
<th>Role</th>
</tr>
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<tbody>
<tr>
<td>General Manager, Clinical Governance</td>
<td>Supports the Chief Medical Adviser in driving system usability and clinical outcomes, implementation and monitoring of a clinical governance framework and safety methodologies</td>
</tr>
<tr>
<td>Chief Medical Adviser</td>
<td>Responsible for clinical input to the strategy and design of the national digital health systems, driving system usability and clinical outcomes inclusive of all aspects of clinical and consumer engagement and for the development, implementation and monitoring of a clinical governance framework</td>
</tr>
</tbody>
</table>

6.2 Clinical and consumer engagement in co-production

Effective engagement with end users (clinicians and consumers) is recognised as a key enabler for the Agency to understand their needs. The Agency engages with clinicians and consumers in the design and development lifecycle of digital health products and services through co-production processes with a user-centred design approach.

6.2.1 Embedding consumers and clinicians in design teams

For each co-production project, the Agency assembles a Core Design Team (CDT) – a multidisciplinary group of experts from various backgrounds – who are the ‘doers’ in the design process. This includes clinicians (including clinical reference leads) and consumer representatives, to contribute their relevant expertise to support the development of the product or service.

Clinical experts are involved at all stages in the product development lifecycle to optimise the utility and effectiveness of the product or service design. The co-production approach is complemented by a focus on user-centred design in the development of the Agency’s digital health products and services.

6.2.2 Clinical assurance sign off

Clinical governance activities are embedded as part of the Service Delivery and Design Framework [5].

Sign off is achieved from the Chief Medical Adviser who leverages the clinical governance related committee structure.

6.2.3 User-centred design

It is recognised globally that the user-centred design approach is a critical success factor for developing and implementing large-scale digital health initiatives (Wachter RM report to NHS [10]). This approach involves focusing the design of a product around the perspectives of the user, to comprehensively understand and appreciate their context, needs, behaviours, workflows and end-to-end experience with the product or service. This understanding then drives iterative design and development processes of products and services to deliver a positive end-to-end user experience.

The Agency’s commitment to clinical and consumer engagement is exemplified through the co-production approach, which the Board mandates at all levels throughout the organisation. Co-production necessitates a strong partnership with consumers, clinicians and other participants to actively support the development of the products and services that they will use. Defined design
decision gates and operational and strategic safety and quality oversight provided by established committees provide opportunities for resolution of challenges identified during the design and development process. This approach augments product readiness and clinical endorsement for release.

The level of integration of consumer representatives and clinicians into project teams in line with the co-production approach is managed, monitored and measured across the Agency through regular collaboration with the Clinical Governance Branch.

To further engage with clinicians, the Agency uses the clinical reference leads who provide advice and insights into its activities and projects by engaging them early in design and development processes.

6.2.4 Embedding clinicians in design teams
Clinicians are integrated into project teams early in the product design and development lifecycle and are selected based on their clinical experience, credentials and the insights which they may bring to the process. By being embedded into project teams, clinicians are empowered to contribute:

- clinical advice on the design or development of a product or service
- clinical use cases and user stories contemporary expert advice to clinical requirements
- oversight and clinical assurance of the clinical effectiveness, usability, quality and safety of the Agency’s product or service
- clinical practice advice into clinical safety assessments
- recommendations for resolution through the established clinical safety and quality governance arrangements detailed in the committee structures (Section 6.1).

Not all clinicians are trained in product or service development projects. To educate and uplift the capability and the effectiveness of the clinician as an equal member of co-production project teams, the Agency has internal training resources available to support them.

The Innovation and Development Division has a Design Branch that brings together the relevant experts in usability and design and focuses on developing a partnership with the users and the clinical assurance teams to design and develop products that are useful, usable and safe.

6.3 Clinical risk management lifecycle
The Agency has adopted an explicit, proactive approach to clinical risk management. The clinical risk management lifecycle (CRML) in Figure 8 is the foundation for this approach. The lifecycle is applied in an adaptive manner depending on the design, clinical need and development method (e.g. agile or waterfall development).
The CRML enables the application of two perspectives:

1. Prospective clinical safety analysis focuses on known clinical hazards and the associated potential clinical risk. The aim is to eliminate or prevent clinical risk. This is achieved through clinical assurance activities in design and development phases.

2. Reactive clinical safety management focuses on reducing or mitigating the effect of a cause of clinical risk. The aim is to ensure the safety control is effective in reducing the impact, considers existing controls and is proportionate to the risk. Clinical event and incident management and learnings inform this activity.

**6.3.1 Clinical safety management system**

The objective of the clinical safety management system (CSMS) [11] is to minimise the risk that the introduction of a new product or service, or change to an existing product or service, could pose to healthcare consumers. The CSMS sets out comprehensive processes to ensure that a set of activities tailored to the product or service are completed. The output of these processes and activities is a defensible clinical safety case. The clinical safety case is maintained for the lifetime of the product or service through to decommission.

The CSMS is underpinned by the following principles:

1. The CSMS will be used to manage the risks from design of digital health products and infrastructure designed by the Agency to fulfil specific use cases. Deviation from the use cases would require additional clinical safety assessment.
2 The clinical safety team will tailor deliverables according to visibility of the Agency project and program governance and documentation.

3 The CSMS has been designed to be flexible according to the agreed product development lifecycle. Agreement with the product areas on the approach is essential.

4 Mentoring is provided to all staff applying the clinical safety management system.

Other key features of the CSMS include the incorporation of relevant international risk management standards, an outline of the methodology for clinical safety management and the roles and responsibilities of the accountable personnel.

6.3.2 Operational risk management

The clinical risk management lifecycle includes an operational focus. The clinical risk management phases as described in Figure 8 apply during the deployment of a product or service and continue through its lifetime. Clinical risk management of operational products or services is reactive to identified clinical hazards, hazardous situations or actual patient harm events.

The main objectives of the clinical risk management phases (CRMP) is to assess the clinical risk associated with an identified or reported clinical hazard or risk, determine what (if any) additional safety controls are required, and implement any additional controls and monitor the effectiveness.

It is essential that the assessment is completed in collaboration with the product owner. The product owner determines which practicable precautions are reasonable, based on factors such as adoption, time, clinical use and cost.

6.3.3 Management of clinical reportable events and incidents

Comprehensive clinical events and incidents monitoring, reporting and management are critical components of the clinical risk management lifecycle.

The Agency recognises that digital health products and services have the potential to contribute to patient harm. The Standard Operating Procedure – Clinical Event and Incident Management enables the response to, and management of, clinical events and incidents to be proportional to the cause and impact.

A 365-day 24/7 support is provided by the Clinical Team to ensure that clinical safety subject matter experts and healthcare providers (known as Clinical Reference Leads) are available to undertake any actions required and support investigations and outcomes that address clinical safety risk and impact. Figure 9 shows the relationship between the Clinical Governance Framework, this document, and the Agency Incident Management Framework and related procedures.

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6.3.4 Identifying and reporting a clinical event or incident

Actual or potential clinical events and incidents reported to the My Health Record incident manager are referred to the Agency Clinical Incident Management Branch as soon as they are identified. Partner organisations, third-party developers, software vendors and healthcare participants who use the Agency’s digital health products and services are engaged by the Agency to investigate, analyse, resolve the clinical event or incident and determine the root cause, including taking actions required to mitigate any immediate risk of a harm event.

In the event of a major, unexpected and disruptive clinical event or incident, other response avenues will be activated, including the Agency business continuity plan, disaster recovery plan and crisis management.

Outcomes of clinical event or incident investigations will be captured, monitored and reported to:

- Identify opportunities to improve event and incident management processes and governance
- Drive future changes that may be required to improve the Agency’s products or services
- Report patterns of issues or problems that require a different approach or wider communication
- Support the External Assurance Committee in providing oversight of clinical event and incident management.

6.3.5 Delivering clinical event and incident management

It is an underlying principle of the Agency that the My Health Record system must operate in an environment of transparency, where issues and concerns are reported and acknowledged without fear or blame and where healthcare providers, patients and their families are told what went wrong and why.

The objectives of the Clinical Event and Incident Management Standard Operating Procedure are to:

- Assist with timely and effective management of clinical events and incidents
- Establish a standard approach to clinical event and incident management
- Ensure a consistent and coordinated approach to the identification, notification, investigation, and analysis of events and incidents with appropriate action
• Allow the lessons learned to be shared across the whole health system
• Provide an essential resource for developing the skills required to effectively manage all digital health clinical events and incidents.

Management of clinical events and incidents requires several steps to be taken, including:
• Assessment of risk
• Taking any action necessary to address the immediate risk
• Short to mid-term actions to manage the event or incident and make improvements to impacted systems
• Long term actions required through referral for further management
• Ensuring end users are kept informed of outcomes that impact them.

The clinical safety management system provides the techniques and processes to deliver clinical event and incident management and guides their clinical safety assessment.

Sufficient resources should be allocated to support the event and incident management program. Analysis of clinical event and incident data is required to continuously improve the safety and quality of the My Health Record system and clinical event and incident management.

6.4 External assurance

6.4.1 External Assurance Committee
The Agency and the ACSQHC have established an External Assurance Committee (EAC). This committee is chaired by a representative of the ACSQHC and provide advice directly to the Agency Chief Executive.

The purpose of the EAC is to provide independent, expert opinion on clinical safety, quality and governance for the Agency. The role and function of the committee is to:
• Review risk and incident cluster analysis and deep dives of critical clinical events and incidents
• Develop an annual safety report which is provided directly to the Chief Executive Officer
• Review the Agency’s Clinical Governance Framework every three years
• Assess the safety and quality performance of the Agency
• Provide advice as required directly to the Chief Executive Officer.

These roles and functions will be aided by the oversight of a range of risk, event and incident reports, detailed in Section 7 of this framework.

6.4.2 External evaluation of clinical governance
The Agency Clinical Governance Framework will be evaluated every three years by the External Assurance Committee. The evaluation process is aimed at determining whether the existing framework is sustainable, fit for purpose and aligned to the Agency’s priority areas for delivery to 2022.
The framework revision incorporates the following reviews and reports.

**Table 3 - Clinical Governance Framework evaluation**

<table>
<thead>
<tr>
<th>Revision collateral</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Clinical risk reports</td>
<td>Reports cover the status of known clinical risks relating to Agency digital health products and services</td>
</tr>
<tr>
<td>Clinical event and incident reports</td>
<td>Reports covering known clinical events and incidents relating to Agency digital health products and services</td>
</tr>
<tr>
<td>Clinical governance key performance indicators (KPI) reports</td>
<td>Clinical governance KPI reports will show how various Agency products and services, either in development or in production, have met the agreed key clinical governance KPIs</td>
</tr>
</tbody>
</table>
| Internal Agency safety and quality reviews | Review of staff level of awareness of the:  
- safety and quality culture  
- clinical governance key components related to the effectiveness of existing policies, processes and frameworks  
- the main clinical governance KPIs measured and reported |
| External Agency safety and quality reviews | Consumers and clinician’s evaluation of the Agency’s clinical safety, quality, as well as outcomes from the Agency’s products and services |
| Agency work plans and National Digital Health Strategy | Assess Agency priority areas for delivery to 2022 |
| Other | The Executive Assurance Committee may also conduct other activities to assess overall Agency clinical governance performance |

The evaluation process and the reporting are carried out by the External Assurance Committee and provided to the Agency Chief Executive Officer.

The Agency Chief Executive Officer may also at their discretion, request the External Assurance Committee to review and report on additional areas.
7 Quality performance and evaluation

The Agency Clinical Governance Framework is reinforced with regular performance monitoring and evaluation measures that support the framework’s guiding principles and the delivery of clinically safe and high quality digital health products and services to the Australian population.

7.1 Safety and quality performance reviews

The Agency conducts internal and external reviews that incorporate safety and quality issues to monitor the successful understanding and implementation of the framework.

7.1.1 Internal review

These reviews are distributed to Agency staff for self-evaluation purposes, to determine the level of awareness around:

- Safety and quality culture
- Clinical governance key components related to the effectiveness of existing policies, processes and frameworks
- Clinical governance KPIs being measured and reported.

The review also seeks feedback and suggestions for improvements to the above three areas.

7.1.2 External review

These reviews are conducted with selected consumers and clinicians to evaluate clinical performance in relation to the Agency’s digital health products and services. The consumers and clinicians are requested to rate the clinical safety, quality and outcomes from the Agency’s products and services.

The Agency’s Clinical Governance Committee will be responsible for the design, distribution, collection, analysis and reporting of both reviews and their feedback, including improvement recommendations.

Review reports and results will be submitted to the External Assurance Committee which will provide advice and recommendations to the Chief Executive Officer.

7.2 Performance reporting

The Agency’s Clinical Governance Committee also has oversight of the reports outlined below. Collectively, as described in Section 6.4.2, these reports will be inputs for the development of the periodic evaluation of this Clinical Governance Framework.

7.2.1 Clinical risk reports

As part of the organisational clinical governance monitoring processes, these cumulative periodic reports cover the status of known clinical risks relating to Agency digital health products and services. They will include recommendations for mitigation and/or remedial actions as well as progress on the implementation of these recommendations.
7.2.2 Clinical event and incident reports

In addition to the clinical risk reports above, cumulative periodic clinical event and incident reports covering known clinical events and incidents relating to Agency digital health products and services. They will include recommendations for mitigation and/or remedial actions as well as progress on the implementation of these recommendations.

7.2.3 Clinical governance reports

As part of the Agency Quality Framework [13], the organisational governance (pillar) will include key performance indicators for key Clinical Governance Framework requirements for the Agency’s products and services, such as:

- Extent of co-production
- Product life cycle gating and signoff.

Twice-yearly clinical governance reports will show how various Agency products and services, either in development or in production, met their key clinical governance KPIs. This will allow continuous improvements in the way the Agency works, as well as how KPIs are measured.
# Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACSQHC</td>
<td>Australian Commission on Safety and Quality in Health Care</td>
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<td>APS</td>
<td>Australian Public Service</td>
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<tr>
<td>CSMS</td>
<td>Clinical Safety Management System</td>
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<tr>
<td>Framework</td>
<td>Clinical Governance Framework</td>
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<tr>
<td>My Health Record system</td>
<td>The My Health Record system Previously known as the Personally Controlled Electronic Health Record system</td>
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<tr>
<td>TGA</td>
<td>Therapeutic Goods Administration</td>
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# Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Meaning</th>
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<tbody>
<tr>
<td>clinical risk</td>
<td>A situation that will result in a near miss or a patient harm event</td>
</tr>
<tr>
<td>hazard</td>
<td>A condition or event that can lead to or contribute to patient harm. e.g. poor patient identity management</td>
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<tr>
<td>cause</td>
<td>A condition that is prerequisite to a consequence; something that fails, malfunctions, doesn’t perform as designed/expected, a credible deviation, etc. e.g. data entry error, poor integration, records management</td>
</tr>
<tr>
<td>hazardous situation</td>
<td>The manifestation of the cause of hazard within a clinical setting / workflow. e.g. real use of a record where wrong information is included because of poor identity management</td>
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</table>
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