Clinical Governance

Performance Report 2023–2024

Australian Government
Australian Digital Health Agency

Chair's Message

Dear Ms. Cattermole, PSM,

I am pleased to present the third Clinical Governance Performance Report for 2023–24 on behalf of the Clinical Governance Committee. This report underscores our dedication to clinical governance excellence and person-centred care in digital health.

This year, we have made substantial strides in several key areas. The introduction of new clinical safety protocols will improve our ability to detect and mitigate preventable adverse events. Our internal Clinical Governance team continues to deliver and evolve programs that support the integration of the Agency's Clinical Governance Framework for Digital Health, ensuring our staff are well-equipped to incorporate clinical governance principles into their daily work.

A notable addition this year is the increased involvement of our Digital Health Adviser Service, with the inclusion of two consumer advisers into the core Clinical Governance Committee membership. Their expertise and personal digital health experiences are helping us bring a stronger consumer focus to our work.

Furthermore, our Agency, supported by the Australian Commission on Safety and Quality in Healthcare, is leading discussions on clinical governance in digital health with our Australian and international partners. This positions us as leaders and stewards in the rapidly evolving digital health field. As we move forward, the Agency remains committed to building on our achievements and pursuing ongoing quality improvement.

It has been my greatest honour to serve as the Chair of the Clinical Governance Committee over the past few years. I am confident that, with the support of the incoming Chair, Dr. Amandeep Hansra, this important work will continue to drive lasting and sustainable change.

Dr Steve Hambleton
Chair, Clinical Governance Committee (2023–24)
Former Australian Digital Health Agency Chief Clinical Adviser

Chief Executive Officer's Message

This year has been truly remarkable for clinical governance at the Agency. From the outset of this financial year, we embarked on an ambitious program, and our safety and quality agenda has continued to expand its influence across our organisation and the broader health and care sector nationwide. Clinical governance is a cornerstone of Australia's National Digital Health Strategy, focusing on the integration of safety and quality throughout the entire health ecosystem to ensure effective care delivery now and in the future.

As an agency, we have consistently embedded our foundational Clinical Governance Framework for Digital Health within the organisation, building on the significant successes of the past year. Our systematic approach to implementing clinical governance practices has garnered positive feedback across the Agency, fostering a shared commitment to ensuring our products and services are safe, fit-for-purpose, and meet the needs of all Australians.

I am immensely proud of the progress highlighted in this report. The Agency's clinical governance practices continue to guide digital health in Australia towards a healthcare system that is digitally enabled, person-centred, inclusive, and data driven.

Leading much of the extraordinary work in 2023–24, was the Agency's former Chief Clinical Adviser, Dr. Steve Hambleton. As Chair of the Clinical Governance Committee and Co-Chair of the Clinical Reference Group, Dr. Hambleton played a crucial role in driving transformational change, fuelled by his unwavering dedication to patient safety and high-quality care in digital health.

I also extend my heartfelt thanks and appreciation to the Clinical Governance team and the members of the Clinical Governance Committee. Your efforts have been the driving force behind the significant and impactful work described in this report, continually advancing towards an inclusive, sustainable, and healthier future for all Australians through connected and digitally enabled care.

Amanda Cattermole PSM
Chief Executive Officer,
Australian Digital Health Agency

Contents

Executive Summary

Welcome to the Clinical Governance Performance Report for 2023–24! This report showcases the Australian Digital Health Agency's (the Agency's) comprehensive approach to clinical governance and our achievements in improving safety protocols, managing clinical incidents, expanding consumer involvement, and leading national and international collaborations. These efforts contribute to driving information sharing, a key strategic objective.

This year the Agency's focus was on embedding clinical governance principles in all aspects of work, guided by leadership, continuous improvement, and a strong focus on consumer needs. We successfully integrated clinical governance into the Enterprise Portfolio Management Office workflows through the development and implementation of the Clinical Safety Risk Dashboard for real-time clinical risk management. We introduced new clinical safety protocols and expanded the Clinical Safety Service to support all Agency programs.

The Clinical Incident Management Service completed over 700 clinical reviews and managed hundreds of clinical support cases, enhancing incident reporting and data capture through ServiceNow. These efforts ensure that health products and services meet consumer needs and intended outcomes, minimising the risk of harm from technology changes and data interoperability issues.

Consumer involvement was enhanced with the addition of two consumer advisers to the Clinical Governance Committee, bringing a stronger consumer focus to our initiatives.

The Agency's leadership extended both nationally and internationally, with the establishment of the International Digital Health Interest Group and the National Clinical Governance in Digital Health Community of Interest.

The Digital Health Adviser Service expanded to over 50 professionals and consumers, contributing expert advice and guidance to over 60 projects.

The Clinical Reference Group provided valuable insights into clinical safety, accessibility, and inclusiveness to guide the Better and Faster Access to Pathology and Diagnostic Imaging program. This Program will continue to be a priority, with ongoing stewardship to ensure the program's success and safety.

The Clinical Governance and Assurance Branch integrated clinical functions across the organisation, supporting the design, development, and delivery of safe, effective, and person-centred digital health products. This included providing leadership, education, and advice on digital health initiatives.

Results of our staff cultural survey indicates the need to enhance internal communication and education around clinical governance, increase support for non-clinical staff, ensure process consistency, and establish a solid feedback loop.

Looking ahead, the Agency will focus on the ethical use of artificial intelligence in digital health, collaborating with experts to address ethical implications. A partnership with Cancer Australia aims to integrate cancer care guidelines into digital health products, improving access to information and proactive health management.

Key Highlights and Achievements

Enhance Clinical Safety and Clinical Incident Management Services

- Introduction of new clinical safety protocols aimed at reducing preventable adverse events.
- Expansion of the Clinical Safety Service, now supporting 100% of Agency programs and projects.
- Launched the Clinical Safety Risk Dashboard for real-time monitoring and reporting of clinical risks, enhancing proactive risk management.
- Effective management of clinical incidents, with a significant number of reviews and high-priority incident responses.
- Increased team size and capabilities to manage clinical risks 24/7, improved incident reporting processes, and published SOPs for managing electronic prescribing incidents.

Clinical Governance Integration

- Successfully embedded clinical governance into the workflows of the Enterprise Portfolio Management Office ensuring clinical risk is tracked and monitored across the Agency.
- Conducted a staff survey to understand the culture of clinical governance, identifying areas for improvement.
- Piloted a Clinical Governance Self-Assessment Tool for staff to evaluate adherence to clinical governance principles, supporting continuous improvement.
- Delivered a six-part educational series on clinical governance principles, increasing staff awareness and understanding.

Digital Health Adviser Service

- Increased involvement of Digital Health Advisers (DHAs) in over 60 projects, providing critical insights and expertise.
- Expanded the panel to include consumers, enhancing product and service design to better meet consumer needs.
- Conducted two major workshops attended by over 45 DHAs.

Clinical Governance Committee

- Updated the Terms of Reference for the Clinical Governance Committee, including the addition of consumer representatives, enhancing the consumer focus in our initiatives.
- Met seven times and reviewed around 50 papers tabled from business areas across the Agency to demonstrate alignment with our five clinical governance principles.

Leadership and Collaborative Efforts

- Strengthened partnerships with the Australian Commission on Safety and Quality in Healthcare and international stakeholders.
- Establishment of the International Digital Health Interest Group and the National Clinical Governance in Digital Health Community of Interest for global and national collaboration and knowledge sharing.

Clinical Reference Group

- Established to support the Better and Faster Access reforms and bring clinical and lived experience perspectives to improved sharing of pathology and diagnostic imaging reports to My Health Record

Digital Health Adviser Service

Engaged over **50 Digital Health Advisers (DHAs)**

Provided **100's of hours of advice and leadership**

Participated in over **60 projects** (33 more than last year)

2 x DHA workshops attended by over 45 DHAs

Clinical Safety and incident management Service

Expanded support from 78-100% of programs and projects

Made **12 formal recommendations** across **7 projects**

Completed **706 Clinical reviews**

Managed **23 high priority incidents**

Managed a total of **319 clinical support cases** (182 with clinical risk rating of medium or higher)

First Clinical Safety Risk Dashboard

Team grew from **2-4 full-time staff**

Onboarded **3 additional healthcare providers and trained 8 clinicians** for on-call clinical incident management role
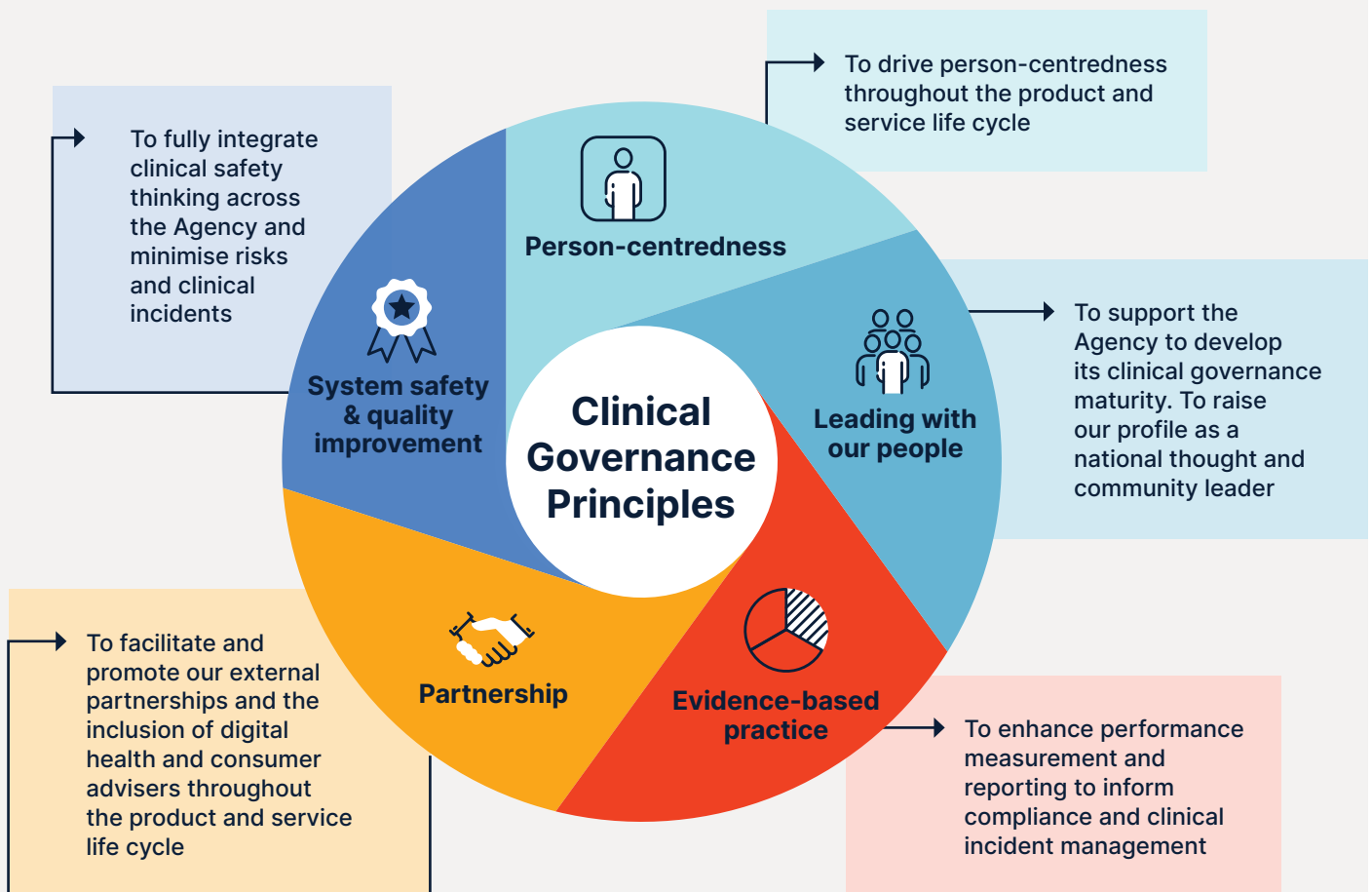
Survey

Conducted inaugural clinical governance culture survey of Agency staff

Clinical Governance in the Australian Digital Health Agency

Welcome to the Australian Digital Health Agency (the Agency) Clinical Governance Performance Report 2023–24! This year, we have established a robust foundation for implementing the Clinical Governance Framework for Digital Health[1] (Framework).

At the Agency, clinical governance is a shared responsibility that connects every member of our workforce and partners. Our Framework fosters a culture of safety and quality through leadership, continuous monitoring, and improvement methods aimed at achieving better health outcomes.

Our efforts are always guided by **five** key clinical governance principles:

To fully integrate clinical safety thinking across the Agency and minimise risks and clinical incidents

To drive person-centredness throughout the product and service life cycle

To support the Agency to develop its clinical governance maturity. To raise our profile as a national thought and community leader

To facilitate and promote our external partnerships and the inclusion of digital health and consumer advisers throughout the product and service life cycle

To enhance performance measurement and reporting to inform compliance and clinical incident management

System safety & quality improvement

Person-centredness

Leading with our people

Clinical Governance Principles

Partnership

Evidence-based practice

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1. Clinical Governance Framework (digitalhealth.gov.au)

Clinical governance is as vital as our financial, risk, and other corporate responsibilities. Everyone at the Agency is accountable to the Australian community, committed to delivering accessible, clinically safe, person-centred, effective, high quality and ever-improving products and services.

This year, we have made significant progress. The Enterprise Portfolio Management Office (EPMO) has successfully integrated clinical governance into their workflows including the tracking and monitoring of clinical risk through their Project Portfolio Management tool. This ensures that clinical governance is deeply embedded in our operations, enhancing the design and management of our digital health products.

We also have a legal responsibility to:

- Reduce fragmentation, improve the availability and quality of health information, and reduce adverse events.2

- 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.3

We are privileged to collaborate with leading experts, clinicians, and Australian healthcare consumers. Together, we demonstrate that strong clinical governance is at the core of every safe and effective digital health product and service. This collaboration is a cornerstone of Australia's National Digital Health Strategy, emphasising embedding clinical governance across the health ecosystem. For example, our Clinical Reference Group has provided crucial insights into system design and clinical safety for pathology and diagnostic imaging.

We've expanded our Clinical Governance team to support ongoing progress, reflecting a broader shift towards adopting clinical governance practices throughout the business. While the Agency baseline culture survey results indicated room for improvement, we acknowledged the need to engage staff more broadly and effectively around the importance of clinical governance in their specific business areas.

During the reporting period, we delivered an extensive clinical governance program spanning internal, external, and international settings, supporting the Agency's strategic goals. This report summarises our clinical governance activities, providing performance metrics to track our clinical governance maturity journey.

We recognise that we still have work to do, but the foundations are in place for meaningful, sustainable organisational change, supported by the ongoing commitment and dedication of our clinical governance staff and Digital Health Advisers (DHAs).

In February 2024, the Agency delivered its next National Digital Health Strategy 2023-28, setting out a 5-year vision and pathway for Australia's digital health future. This strategy emphasises building an inclusive, sustainable, connected system informed by stakeholders with lived experience ensuring alignment with the broader digital health goals.

The world of digital health is rapidly evolving, transforming how health and care are provided and experienced globally. Digital health opens new possibilities, like expanding information at the point of care, enabling connected care, and streamlining processes to minimise errors, promising better health outcomes and experiences for the Australian community.

2.   My Health Records Act 2012, Part 1, Section 3

3.   the Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016 (Cth) Part 2, 9(1)(d)

Clinical Governance and Assurance Branch

The Clinical Governance and Assurance Branch (CGAB) aims to integrate clinical functions across the organisation to support the design, development, delivery and stewardship of safe, effective and person-centred Australian digital health products and services.

In 2023–24, CGAB operated within the Policy, Programs and Engagement division (PPED), led by the Chief Program Officer.

Figure 1: Australian Digital Health Agency Organisational Structure
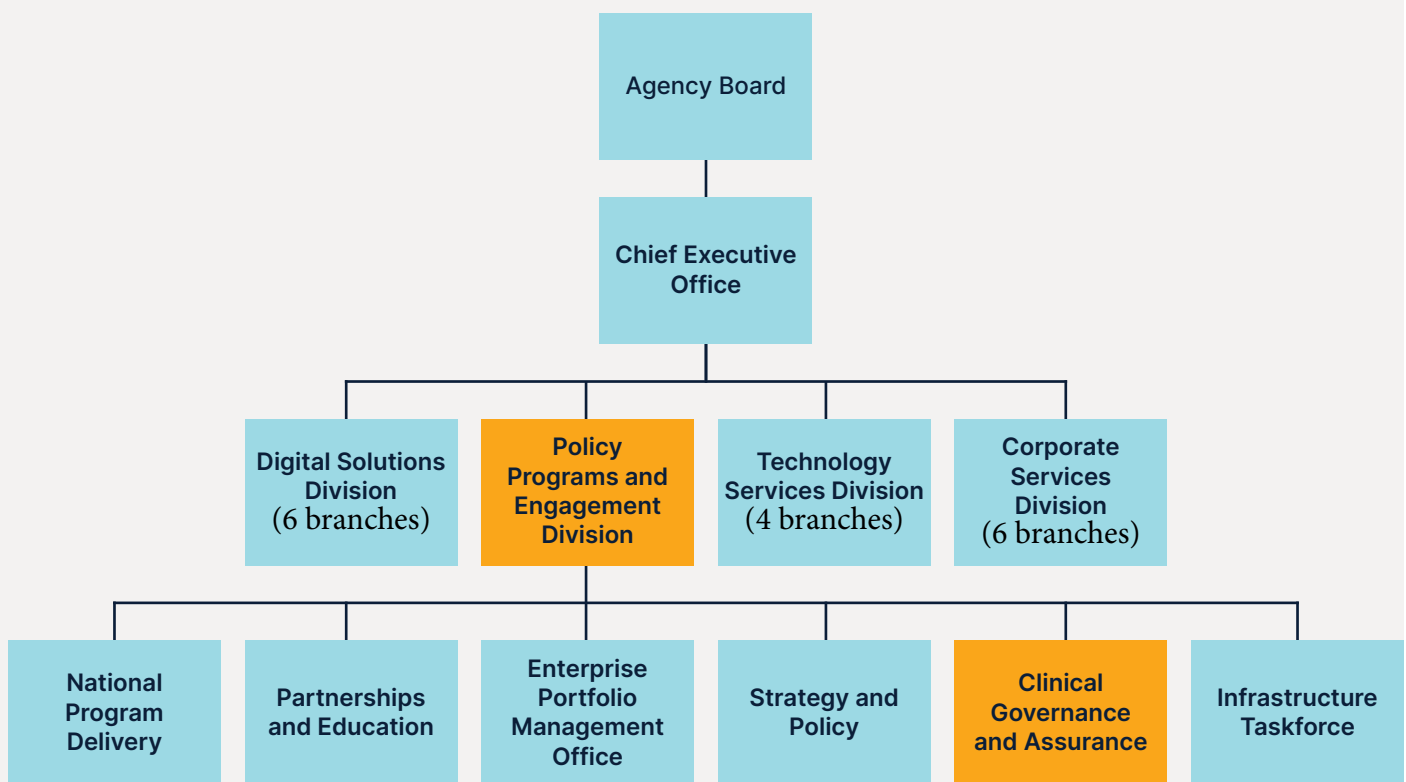
The CGAB deliver key clinical governance functions through the first two branch sections:

1. Clinical Governance Section

2. Clinical Safety and Incident Management Section

3. Compliance Outreach Section

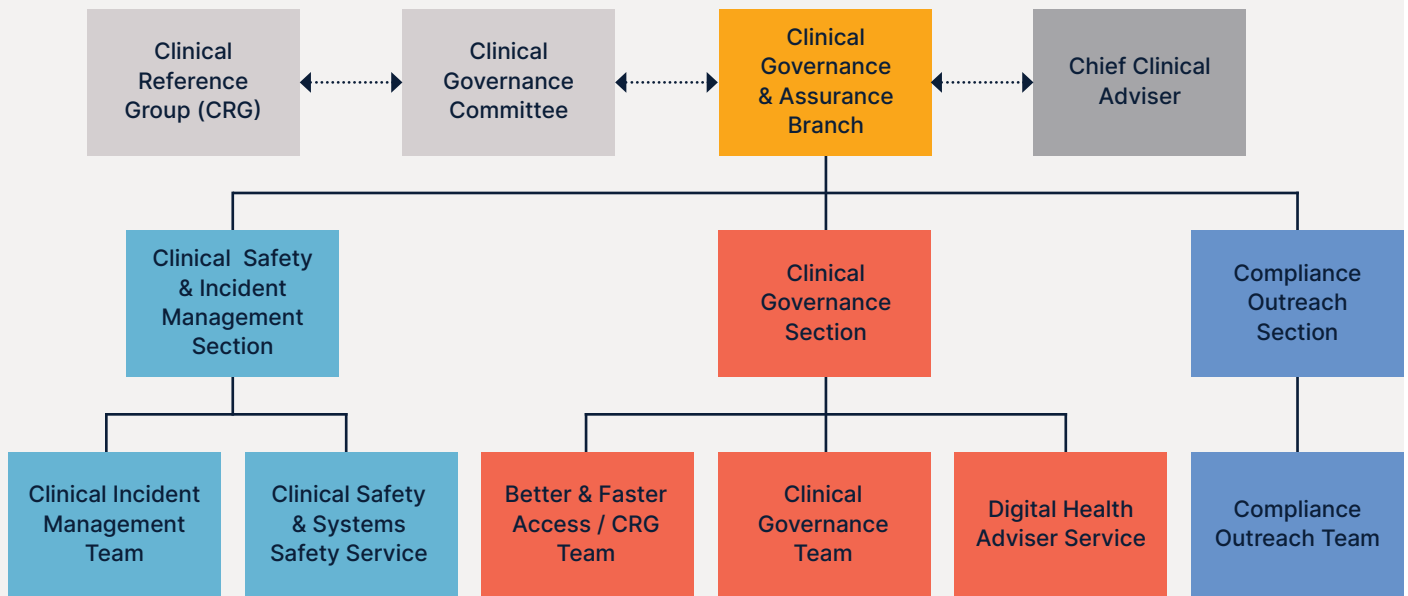**Figure 2: Australian Digital Health Agency Clinical Governance and Assurance Branch Structure**

The CGAB responsibilities include embedding clinical governance through our Framework, providing leadership, education, and advice on digital health initiatives, and coordinating clinical governance practices nationally and internationally. The team deliver clinical safety analysis, advice, and assurance in the design, build, and implementation of systems and products. Additionally, they oversee our partnership with the Australian Commission on Safety and Quality in Health Care (the Commission) and coordinate the DHAs to bring consumer and healthcare provider expertise into product and service development. The CGAB also provide support to the Clinical Governance Committee (CGC).

Figure 3: Clinical Governance Section Functions

Stewarding the Clinical Governance Framework, championing the five principles and driving Clinical Governance Committee

Monitoring organisational performance and maturity by implementing and iterating the Framework resources

Building clinical functions and organisational capability

Working with partners to provide appropriate external assurance

Providing clinical leadership through the Digital Health Advisers

At the heart of everything we do is a commitment to clinical governance, ensuring our products and services are high quality and clinically safe. CGAB work closely with our Chief Clinical Adviser, who supports our Senior Executive Committee and Chief Executive Officer, to deliver programs and projects that meet these exacting standards.

Embedding Clinical Governance across the Agency

Since we published the Framework in early 2023, the Clinical Governance Section program has focused on activities that support growth and maturity of our clinical governance system.

A summary of clinical governance activities completed over the reporting period include.

- Clinical Governance Culture Survey
- Clinical Governance Internal Forum
- Clinical Governance Knowledge Series - a six-part educational series, delivering between August 2023 to February 2024 promoting awareness of the Framework and principles.

- Development of Framework implementation resources
- Piloting and refinement of the Clinical Governance Self-Assessment Tool, Principles Fact sheets and Confluence page.

These achievements were supported extensively by members of the DHA Service who have provided extensive advice along every part of the consultation and development journey.

Assessment of Clinical Governance System Maturity and Performance

This year we aimed to establish a baseline understanding of what clinical governance means for our staff and the work they do.

This baseline data will inform the priorities and next steps for customising the Agency's approach to developing a whole of Agency reporting scorecard that will support oversight of how our Clinical Governance System is maturing and evolving over time where new risks emerge, or significant improvement opportunities are identified.

We anticipate that clinical governance adoption and integration of the Framework principles into the Agency's business-as-usual processes will take time and will be influenced by many factors.

By establishing these baseline measures and consulting widely across the Agency, we are in a strong position to develop practical metrics that will systematically monitor clinical governance implementation and adoption moving forward. The next section gives an overview of the baseline measurement activities actioned during the reporting period.

Clinical Governance Culture Survey Key Findings

In 2024, the Agency set out to understand how the culture of clinical governance was embedded throughout our work. Over six weeks in February and March 2024, we conducted a Clinical Governance Culture Survey. We asked our staff about their understanding and attitudes towards clinical governance, covering a variety of areas like quality improvement, evidence-based practice, clinical safety and consumer engagement. Out of all our staff, 189 (28%) responded to the survey, with representation from all divisions, though most responses came from the Policy, Programs and Engagement Division and the Digital Services Division. This survey is a crucial step in advancing our clinical governance maturity, setting a baseline for future comparison. It also guides our improvement efforts by highlighting key areas to further embed clinical governance principles.

The results suggest the need to:

- enhance communication and education.
- increase practical support and guidance.
- ensure consistency of processes.
- engage non-clinical staff.
- review engagement processes.
- solidify a feedback look to enhance clinical governance.

This feedback is invaluable as we continue to improve and strengthen our clinical governance culture.

Clinical Safety Service

The Clinical Safety Service primarily upholds the Systems Safety and Quality Improvement principle in the Framework. The revised Clinical Safety Management System (CSMS) guides how we identify and manage clinical safety risks in digital health. We classify clinical safety hazards in digital health based on what can potentially reach a person in their health or care and cause an adverse outcome or harm.

We have four generic hazards - incorrect, incomplete, unclear, or unavailable health information. The Clinical Safety Service has been a cornerstone of the Agency's work plan, providing specialist advice and assurance across up to 40 Agency programs and projects at any given time throughout this year. By applying the CSMS, we ensure the safety of our products and services throughout their entire lifecycle – from design and development to delivery, implementation, and maintenance.

Figure 4: Clinical Safety Management System Service Model

Provides an overview of how clinical safety is incorporated into digital health product life cycle.

The **Clinical Safety team** consolidates and uploads all clinical safety product reports and cases to the Clinical Safety Product Library, using findings to improve and identify gaps in the CSMS.

The **Clinical Safety team** engages with project teams to determine clinical safety services and develops a management plan to document deliverables and activities.

The **Clinical Incident Management team** reviews and actions reported national digital health infrastructure product incidents.

Problem management: Managing and resolving the underlying cause

Research & insights: Evidence based solutions & clinical safety data insights

Subject matter experts use the clinical safety design considerations guidelines when designing products that involve using, supporting, or displaying a person's health information.

Incident management: Reactively respond to clinical risks

Experience & product design: Co-design with healthcare providers to identify clinical safety hazards

Research and Planning

Monitoring

Design

Sally
Person at the centre

Education: Change and adoption to promote safe clinical use

Go Live

Deployment

Development

Testing

Responsive clinical risk management

Preventative clinical risk management

Preventative clinical risk management

Conformance: Specify the clinical safety 'guardrails'

Go Live

The **Clinical Safety team** completes a go-live report to assess product clinical safety risks and control measures.

Testing: Identify and rectify defects

Testing teams ensure all activities for Agency products and services follow clinical safety assurance guidelines.

The **Clinical Safety team** holds clinical hazard and risk workshops to identify and manage clinical safety risks collaboratively. These risks are documented and monitored using the Agency's tools, informing the development of conformance profiles.

This year, we are proud to announce that the Clinical Safety Service support has expanded from 78% to 100% of Agency programs and projects, all benefiting from direct clinical safety assurance. This means our Clinical Safety team is now deeply integrated within core design teams, significantly enhancing our preventative clinical risk management efforts. Their scope of work includes – Health Information Exchange (HIE), My Health Record, My Health App, Aged Care, Healthcare Identifiers (HI) Service, Interoperability, Real-Time Prescription Monitoring (RTPM), and Electronic Prescribing.

While the daily impact of the Clinical Safety Service on projects and programs can be challenging to quantify, they made 12 formal recommendations across seven projects this year (My Health Record Releases 23.3.0, 23.5, 24.3 including Medical Conditions View (MCV) Release 24.4, Aged Care Transfer Summary (ACTS), Healthcare Information Provider Service (HIPS) Health Viewer (HV) v1.0). We are pleased to report that all recommendations were accepted and are currently at various stages of implementation and action.

Some key achievements:

Healthcare Information Provider Service (HIPS) HealthViewer (HV) Allergy Display:

- Display and Prioritisation Enhancements:
  - Increased the number of allergies/adverse reactions shown from three to five, to ensure all allergies were displayed for 95% of cases.
  - Expanded terms for severe allergy manifestations, marked with hazard icons and red text, prioritised at the top.
- Improved Accessibility:
  - Added links to direct users to the complete view of allergies and adverse reactions.
- Impacts:
  - Improved safety and usability, ensuring critical information is prominently displayed and easily accessible.
  - Maintained a low clinical risk profile with a user-centred design.

These updates make the HIPS HV system safer and more user-friendly.

Clinical Risk Assessment for Chart-based Electronic Prescription via Active Script Register

- Risk Identification:
  - Potential for multiple dispensations of chart-based electronic prescriptions at different pharmacies without detection.
  - Risk of oversupply if residents or their agents access perpetual prescriptions outside the contracted pharmacy via the Active Script List (ASL).
- Control Measures and Actions:
  - Various control options were assessed for effectiveness.
  - The Electronic Prescribing Conformance Profile requirement (DISP-87) was updated to ensure that tokens for chart-based electronic prescriptions are not displayed. This means that while details about these prescriptions can be shown, the tokens themselves should not be available.

- Impacts:
  - Prevents illegal multiple dispensations of chart-based electronic prescriptions.
  - Ensures that chart-based electronic prescriptions cannot be dispensed without the entire medication chart, reducing the risk of oversupply.

These measures enhance the safety and integrity of the electronic prescription system, ensuring compliance with legal standards and protecting against potential misuse.

Clinical Safety Influence on Medical Conditions View (MCV)

- Risk Assessment and Mitigation:
  - Conducted a consumer-centred risk assessment with various stakeholders.
  - Identified clinical risks and implemented design controls to mitigate them.
- Impacts:
  - Ensures accurate, complete, and contextually preserved information.
  - Enhances the safety and usability of the MCV, benefiting both healthcare providers and patients.

These updates make the MCV a more reliable and user-friendly tool for managing medical information.

Clinical Safety Risk Dashboard

In March 2024, the Clinical Safety team in collaboration with the Data Operations and Analytics team and EPMO, successfully launched the first version of the Clinical Safety Risk Dashboard. This dashboard represents a significant step forward in automating and refining clinical risk management reporting of the Agency's programs and projects. It enhances the Agency's ability to assess, monitor and report on clinical risk, allowing staff to engage with these risks more effectively across the entire program of work. This whole-of-system approach to clinical safety aligns with the Agency's responsibilities under the PGPA Rule.

Notable features of the dashboard include:

- Enhanced risk management: The dashboard fosters a culture of safety by providing real-time insights, enabling the Agency to manage clinical risks proactively.
- Enterprise-wide visibility: It offers a comprehensive view of clinical safety across all EPMO registered programs and projects and throughout the implementation of the National Digital Health Strategy 2023–28.
- Improved governance: Internal Governance committees including the CGC, can have deeper insights into clinical safety risks, enhancing their oversight capabilities.

- Data quality and training: The EPMO and Governance Services can use the dashboard to improve data quality within the PPM tool and provide targeted training for Program Managers on risk recording and management.

The CGC praised the initiative:

"The improved reporting maturity and the integration of clinical governance with technology delivery ensure that we are delivering the right outcomes, ultimately impacting clinical safety."

This dashboard represents a strategic enabler of broader change within the Agency, embedding a culture of safety through real-time insights and proactive risk management. Continuous feedback from stakeholders will drive future enhancements, ensuring the dashboard continually evolves to meet the Agency's needs.

A view of the Clinical Safety Risk Dashboard. The dashboard provides an overview of clinical risks captured in projects to improve risk visibility and support decision making.

Clinical Incident Management Service

The Clinical Incident Management Service (CIMS) is committed to protecting consumer health by managing clinical risks associated with health information. Operating 24/7, CIMS addresses issues like inaccurate, incomplete, or misleading health data that could impact a consumer's health or care. By providing regular reports to the CGC, CIMS helps identify emerging risks and opportunities for system improvements.

CIMS manage clinical risks in reported and detected incidents, coordinate health information-related risks, support electronic prescribing incident coordination, and prepare for real-time prescription monitoring. The service also offers round-the-clock support aligned with the CSMS.

Overall, CIMS ensures that health products and services meet consumer needs and intended outcomes, minimising the risk of harm from technology changes and data interoperability issues.

Leading Clinical Incident Management	Managing Clinical Support cases	Coordinating electronic prescribing incident management	Delivering Real Time Prescription Monitoring incident coordination	Providing 24 hour on-call clinical incident management service aligned to the Clinical Safety Management Service

Some key achievements:

During the reporting period, the CIMS undertook 706 clinical reviews of technology related incidents and provided clinical safety advice on 66 bridge calls. Additionally, CIMS managed a total of 319 clinical support cases focusing on issues such as inaccurate, incomplete, or misleading health data that could affect a consumer's health or care. Clinical support cases address data quality concerns from consumers and healthcare providers to manage clinical risks proactively and rectify the source issues in connected systems.

The number of incidents and cases managed by CIMS is relatively low compared to the volume of health information in My Health Record. At the end of the reporting period, there was approximately 6.3 billion health data files in the My Health Record system, of which about 1.5 billion are documents that have been uploaded by healthcare providers.

The types of cases are categorised below.

Figure 5: Categories of Clinical Support Cases

This figure shows the number of cases managed on behalf of consumers between 1 July 2023 to 30 June 2024. Cases may involve multiple documents or items.

Incorrect clinical documents
120

Incorrect PBS item
93

Other
4

Clinical Support Cases

Incorrect MBS item
11

Electronic prescribing
29

Document transaction failures
19

Intertwined records
21

Missing clinical documents
22

Team Expansion and Training

- The CIMS team grew from two to four full-time staff.

- Successfully onboarded three additional healthcare providers to the on-call pool of DHAs, now totaling six.

- Trained eight clinicians for the on-call Clinical Incident Management Team (CIMT) role.

- All team members completed NHS Digital Clinical Safety Training.

Governance and Reporting

- CIMS became a regular agenda item at the CGC, highlighting its importance in risk management.

- Included in Board reports in May 2024, receiving positive feedback.

- Contributed to a collaborative paper for the Jurisdictional Advisory Committee, to be presented in June 2024.

Capability and Service Enhancements

- Participated in exercises demonstrating effective incident response for extreme clinical risks.

- Enhanced incident reporting and data capture through ServiceNow.

- Published Standard Operating Procedures (SOPs) for managing electronic prescribing incidents.

- Contributed to the Service Integration and Management (SIAM) work, improving the escalation process for major incidents.

- Collaborated with the Clinical Safety team on document development and process improvements.

Digital Health Adviser Service

The DHA Service connects the Agency with the frontline of health and care, ensuring our work is informed by real-world experiences. This service emphasises collaboration and co-design, which are central to our work practice.

Our diverse DHA panel includes professionals from general practice, various medical specialties, nursing, psychology, pharmacy, allied health, informatics, public health and more. In 2024, we expanded to include consumers, enriching our perspective with their insights and lived experiences.

Throughout the year, we held events to maintain the connection between our DHAs and the Agency. Two workshops, attended by over 45 DHAs, covered various digital health topics and provided opportunities to discuss the Agency's priorities and current work plans.

In the 2023–24 budget year, DHAs participated in over 60 projects, 33 more than last year! They provided hundreds of hours of advice, leadership, and guidance on major healthcare initiatives like My Health Record and the Fast Healthcare Interoperability Resources (FHIR) Programs. Their contributions are helping to shape effective and user-friendly products and services to meet the needs of the entire healthcare community.

Figure 6: Demonstrates the value, lived experience and insights that clinical governance adds to the product and service life cycle; to maintain the connection with consumers and the Agency's vision to enable a healthier future for Australians through connected healthcare.

Experience

Products and Services

Outcomes driven
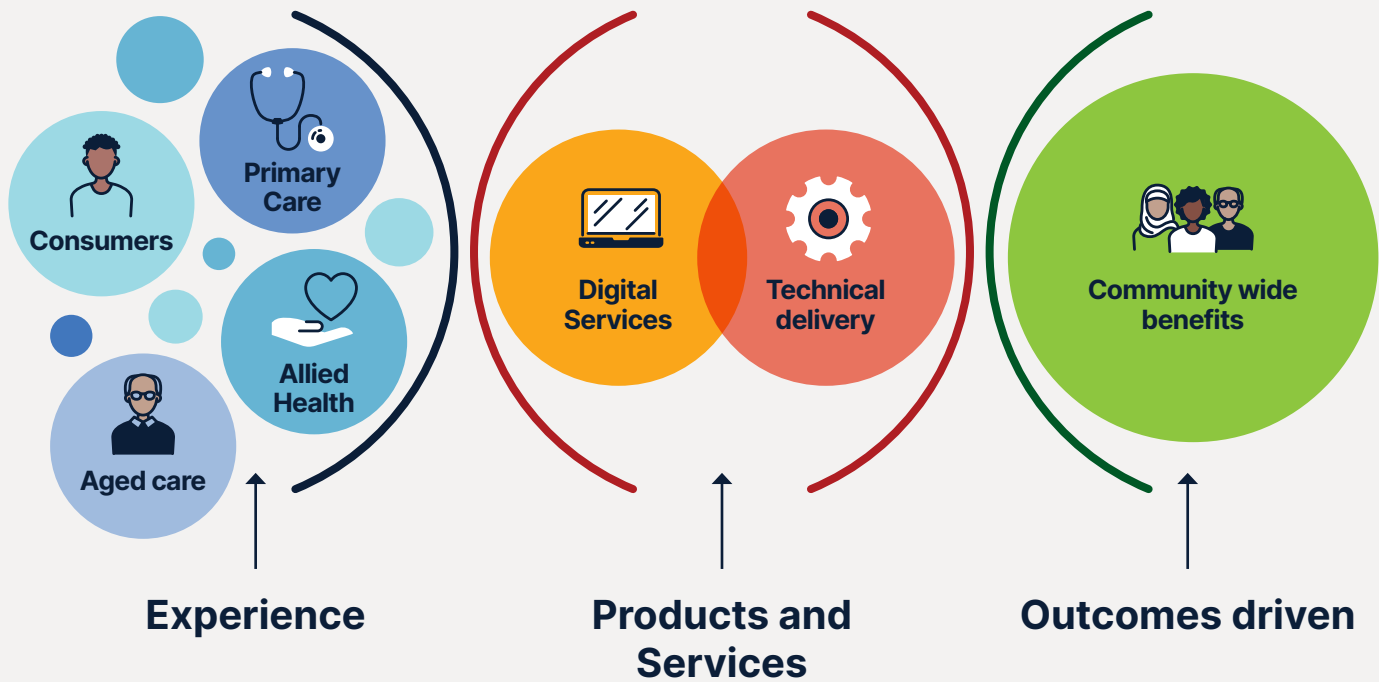
The blend of technical and digital expertise with consumer and healthcare practitioner insights helps the Agency deliver effective products and services. This approach addresses the complex healthcare system at different touchpoints. Consumer DHAs have praised the Agency's work, feeling valued and connected when working with technical and digital teams.

In 2024, DHA management transitioned from the Digital Services Division to the Clinical Governance team. This strategic move strengthened relationships between Clinical Governance, Clinical Safety, and continuous improvement while maintaining connections with broader Agency teams.

Guided by the Agency's work plans, the DHA service team continues to bring in new DHAs, keeping this important connection strong. There are now over 55 DHAs, each contributing uniquely to the Agency's work. You can learn more about them on the Agency website.

Figure 7: This image illustrates how broadly Digital Health Advisers contribute to achieving the Agency's mission of a collaborative environment to accelerate adoption and use of innovative digital services and technologies. The breadth of lived experience across many models of care and service delivery types provides a rich tapestry of insights and implementation considerations to inform clinical governance practices.
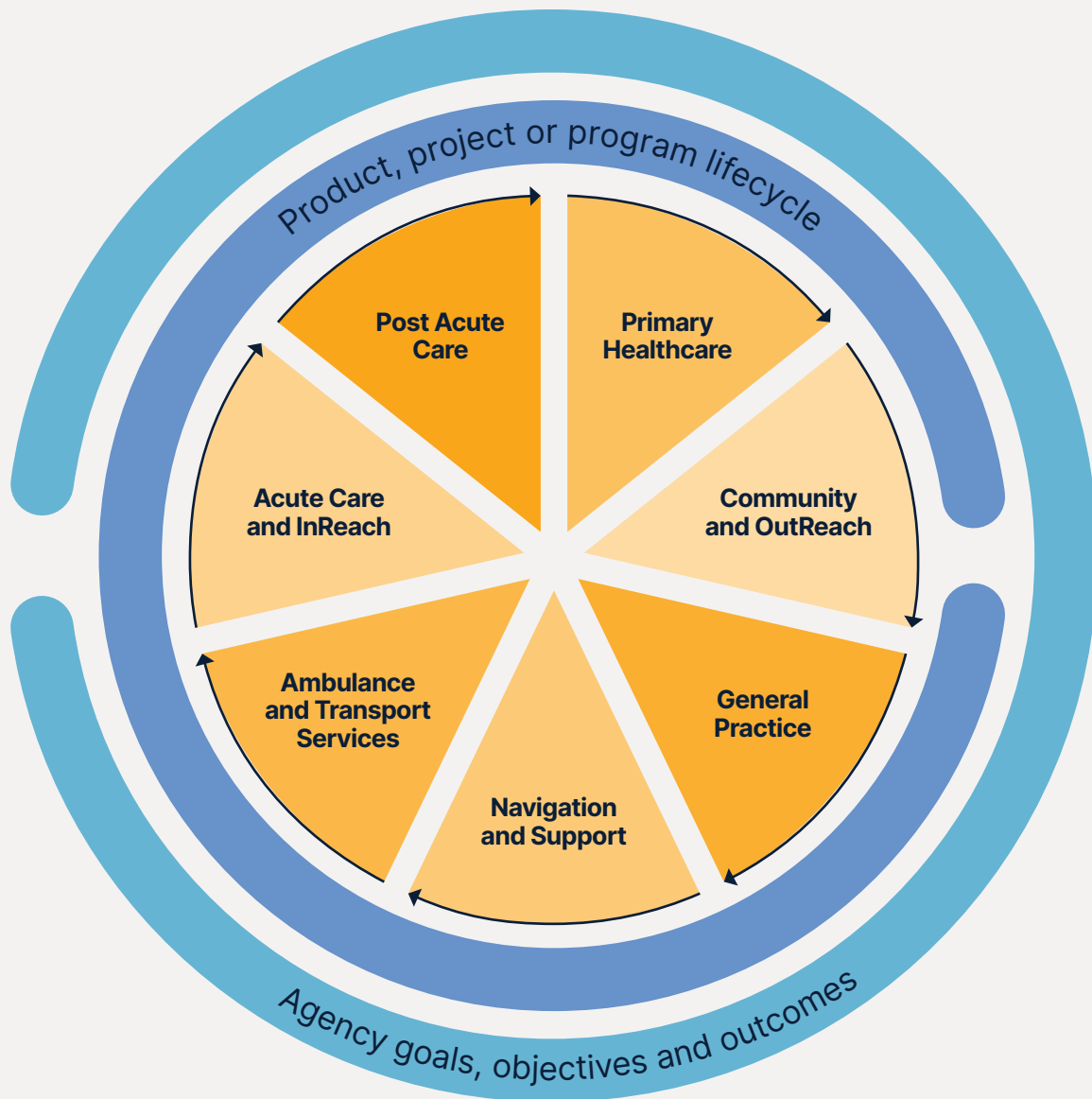
The DHA service team manages engagements and processes to integrate real-world expertise into the Agency's work. They continue to implement recommendations from Project Health in 2022, including revising business processes related to finance and administration. These enhancements ensure the program's efficiency and support a positive culture and involvement of DHAs in line with Agency values and goals.

Clinical Governance Committee

The Clinical Governance Committee (CGC) is our main advisory body ensuring that clinical governance is not just a concept but a measurable practice that underpins the Agency's quality, clinical safety, continuous improvement, and performance agenda.

This committee provides essential technical advice and clinical oversight to our business units, programs, and projects, supporting the Chief Executive Officer in their duties under the PGPA Rule[4].

Chaired by the Agency's Chief Clinical Adviser, the CGC includes members drawn from our division heads, branch managers, clinical governance managers, the Commission, and independent multi-disciplinary clinicians and consumer representatives from our DHA Service. The CGC can call on internal or external subject matter experts and guests to attend meetings, contributing to important discussions such as progression of the National Digital Health Strategy. This collaborative approach ensures that we stay aligned with our strategic goals and continue to improve our services.

In January 2024, our CEO, Amanda Cattermole, approved an updated Terms of Reference for the CGC.

Key changes included:

- Guiding principles – outlining the guiding principles of the Framework.
- Standing membership – increase the number of external clinical members from two up to four and inclusion of two consumer representatives.
- Member responsibilities – addition of Deputy Chairperson role.
- Change in meeting frequency – from monthly meetings to six meetings per year for up to three hours if required.
- Performance review cycle – change from reviewing the ToR annually, to every three years.
- Advice on dissolution of the CGC

Our two consumer representative members joined the CGC in April 2024 bringing valuable perspectives to the table.

The committee receives regular reports from the Incident Management team, the Clinical Safety Service team, and the Enterprise Portfolio Management Office (EPMO). These reports provide members with oversight of current clinical safety and quality risks and issues. During the year the CGC met seven times and reviewed around 50 papers tabled from business areas across the Agency to demonstrate alignment with our five clinical governance principles.

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4. Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016 to implement the five principles of the Clinical Governance Framework (section 6)

One notable example is the Comprehensive Health Assessment Program (CHAP) Integration Project, presented by the My Health Record Expansion and Use section of the National Program Delivery Branch. This initiative aims to digitise and integrate Part 2 of the CHAP tool[5], which includes a follow-up GP assessment and action plan, into GP clinical information systems (CISs). By making the tool more accessible for GPs, the project seeks to improve health outcomes for individuals with intellectual disabilities. The project ensures alignment with the Framework and engages a broad range of stakeholders to enhance the tool's effectiveness and usability. Key aspects include:

- Leading with People: Maintaining open and transparent stakeholder engagements.

- System Safety and Quality Improvement: Incorporating clinical safety, privacy, and cyber advice into the design.

- Evidence-Based Practice: Using research and stakeholder feedback to inform the tool's digital transformation.

- Person-Centredness: Involving GPs, carers, and consumers in the design process.

- Partnerships: Collaborating with CSIRO and other stakeholders make the most of combined efforts.

Figure 8: Illustrates the positioning of the Clinical Governance Committee within the broader Agency governance structure.

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5.   CHAP – Comprehensive Health Assessment Program (https://chaphealth.com/#what-is-the-chap)
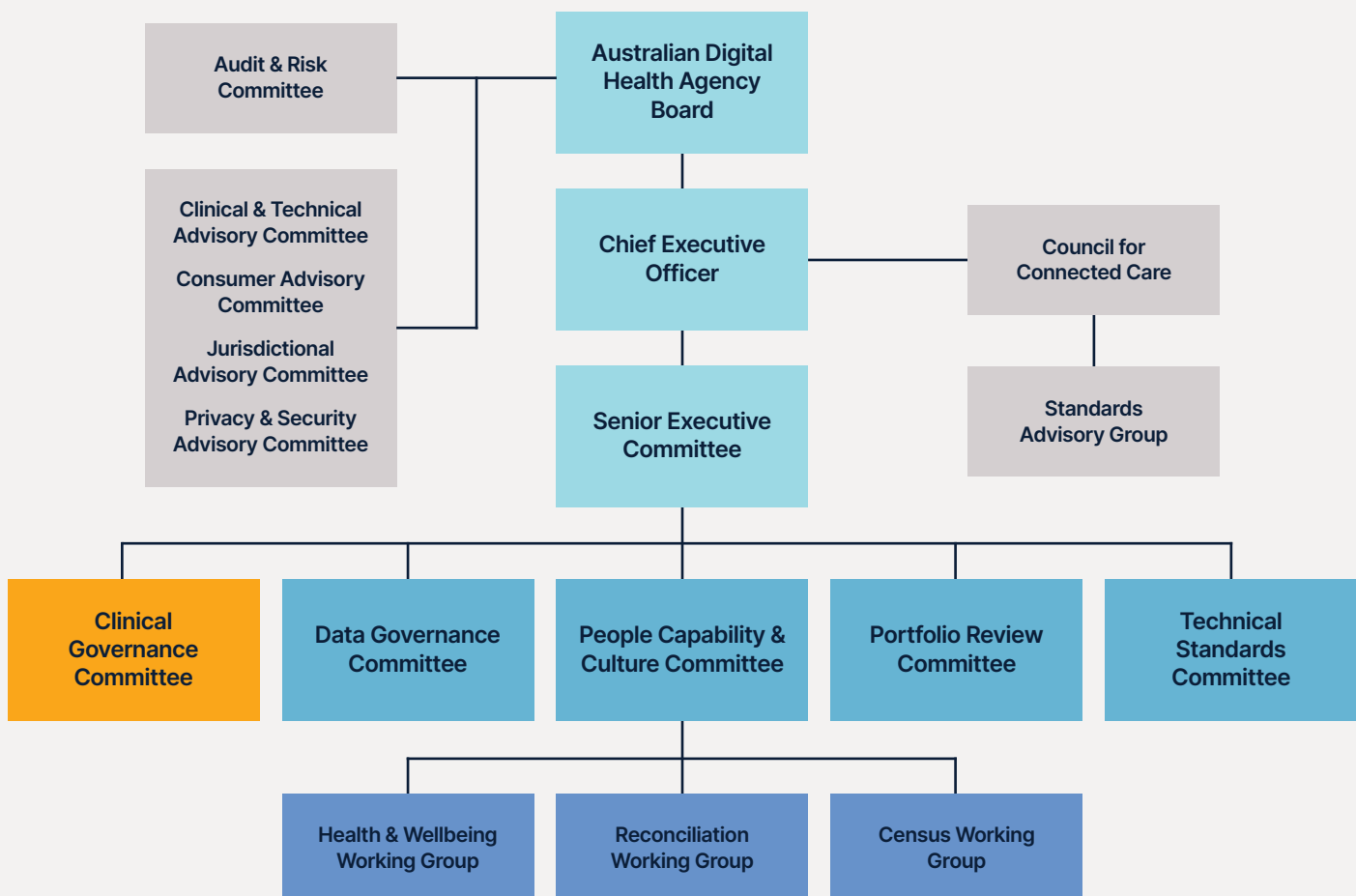
Strengthening Our Collaborative Efforts

Our dedication to leadership and collaboration shines through in our partnerships with stakeholders both nationally and internationally. These collaborations ensure our initiatives are driven by those at the forefront of digital health, continuously enhancing the safety and quality of our systems.

We focus on delivering care that respects and responds to individual patient preferences, needs, and values. In addition to our core advisory groups, these partnerships and forums incorporate diverse perspectives, strengthening our efforts and driving national capability in the healthcare sector.

By sharing expert knowledge and insights, we ensure our clinical governance practices are grounded in solid evidence.

Australian Commission on Safety and Quality in Health Care

Since 2012, the Commission has been formal partner with the Agency, sharing commitment to shaping clinical governance, safety and quality of My Health Record and other digital health initiatives.

Over the 2023–24 period, we had eight productive meetings with the Commission, tackling a range of important topics like aged care, interoperability, medicines safety and unique health identifiers. In January 2024, we refreshed our memorandum of understanding (MOU) to highlight the crucial role both organisations play in promoting safety and quality in digital health, aiming for better health outcomes and experiences for Australians.

The updated MOU set out some exciting priorities for consultation and collaboration:

- Exploring the potential of generative artificial intelligence
- Improving the transfer of care processes
- Clinical trials
- Clinical quality registries
- Enhancing medicines safety
- Expanding Health Identifiers

To keep the momentum going, we have lined up a regular program of meetings and consultations with the Commission throughout 2024–25.

Clinical Reference Group

The Australian Government is making significant legislative and policy changes to My Health Record based on recommendations from the Strengthening Medicare Taskforce Report.

Following the release of the report, the Honorable Mark Butler, Minister for Health and Aged Care, announced policies to enhance healthcare availability and sustainability, modernise the My Health Record and increase consumer health information accessible within each record.

The policy changes will improve sharing of information to My Health Record in two ways:

- Better access – requiring healthcare providers to upload diagnostic imaging and pathology reports.

- Faster access – allowing consumers to see those reports without delay after they are shared to My Health Record.

This will better support health management and care coordination.

To support this reform, the Agency established a Clinical Reference Group (CRG) to guide the *Better and Faster Access to Pathology and Diagnostic Imaging program* led by the Department of Health and Aged Care (DoHAC).

The CRG comprises 24 representatives from relevant peak bodies, professional associations, consumer groups and other stakeholders involved in pathology and diagnostic imaging services. It plays a crucial role in ensuring that clinical safety and lived experience perspectives are considered in the upload of pathology and diagnostic imaging results to My Health Record.

During 2023–24, the CRG met regularly to consider what high quality information should be delivered to clinicians and consumers with an emphasis on clinical safety, accessibility, and inclusiveness.

In preparation for the legislation and policy changes, the Agency gathered advice and recommendations from the CRG on several key areas. These included:

- Identifying clinical scenarios where it may be appropriate not to upload certain pathology and diagnostic reports.

- Establishing key principles to support co-decision making between consumer and clinician at the point of test requesting.

- Determining circumstances where immediate access to reports could pose a risk to health safety or wellbeing.

- Creating a nationally consistent approach to clinical governance and stewardship of the Better and Faster Access program.

- Outlining education and communication requirements for Australians, including those at-risk populations who might be adversely affected by the changes.

The CRG's work will result in a Clinical Safety Implementation Guide, a stewardship and evaluation model for ongoing maintenance, and education resources to support consumers and clinicians.

Looking ahead, the CRG's efforts ensure preparedness for these changes, prioritising clinical safety and the needs of both healthcare providers and consumers. This proactive approach will help us navigate future challenges and opportunities in digital health.

International Digital Health Interest Group

In 2022-23, we established the International Digital Health Interest Group (DHIG) under the Global Digital Health Partnership, focusing on implementing clinical governance principles in digital health. The summit in February 2023 marked the beginning of a vital national conversation, and in May 2024 we held the inaugural meeting of the DHIG. The meeting brought together members from 14 countries to network, collaborate, and initiate a global conversation on clinical governance in digital health. Australian representatives provided an overview of digital health in Australia and the work of the Agency. The representatives also outlined key priorities for clinical governance in digital health. Moving forward, meetings will be held three times a year to continue this important work. The Terms of Reference are available for those interested in further details.

National Clinical Governance in Digital Health Community of Interest

This year we established a National Clinical Governance in Digital Health Community of Interest (COI). This initiative brings together a diverse group of stakeholders including jurisdictional representatives, service providers, digital innovators, software developers and academics. Our goal is to share knowledge and expertise, fostering the growth of clinical governance in digital health practice.

Meetings will occur twice yearly. These gatherings will provide an open forum for discussing national clinical governance in digital health matters, enhancing collaborative partnerships, and sharing expert knowledge. Participants will showcase their expertise and insights, helping set the national agenda for clinical governance in digital health.

Pathways to Excellence: Plans for 2024-25

As digital health services, telehealth, and personalised care continue to grow, robust clinical governance systems and standards are more crucial than ever. These systems support the safe development, implementation, and management of digital health technologies, ensuring high-quality care.

Artificial Intelligence Integration in Agency Products and Services

We recognise the potential benefits of artificial intelligence (AI) and emerging technologies for digital health. Over the coming years we will consider opportunities to harness smarter, more intuitive tools that can help both healthcare providers and consumers, making healthcare more efficient and user-friendly.

Clinical governance is at the core of our approach. We are dedicated to ensuring that any use of AI tools is safe, effective, responsible, and ethically sound. Our efforts will include:

- Stewardship of clinical governance for AI in health care.

- Updating clinical and data governance frameworks to incorporate elements relevant to AI.

- Collaborating with bioethicists and experts to address ethical implications of AI.

We aim to bring together diverse stakeholders to encourage collaboration and adoption of standards and best practices for AI in healthcare. Our plan includes engaging with clinical organisations to unify guidelines and standards to reduce confusion and ensure consistency across the sector. By leveraging our relationships with bodies like the Commission, we can disseminate best practices and gather feedback from the field.

To bring these plans to life, we will:

- Form a dedicated team within the CGAB to focus on the use of AI.

- Explore the ethical challenges posed by AI and develop guidance and training materials.

- Review literature on global trends and best practices in AI clinical governance.

- Update agreements with key partners to clearly define roles and collaborative efforts.

- Identify skills and recruit specialists to drive these initiatives forward.

These plans reflect our commitment to harnessing the power of AI to enhance healthcare while maintaining the highest standards of clinical governance and transparency in the selection and implementation of AI tools. It's an exciting time, and these steps will help ensure that AI is used responsibly and effectively to benefit everyone in the healthcare system.

Cancer Australia Partnership

In alignment with our commitment to enhancing digital health initiatives, the Agency is entering into a MOU with Cancer Australia. This collaboration aims to integrate cancer care guidelines and optimal care pathways into our digital health products, expand the scope of clinical documents available through My Health Record and promote greater digital enablement for Australians, particularly those living with cancer.

The Agency will provide technical advice on digital health initiatives, support the development of new digitally enhanced guidelines, and identify opportunities to include Cancer Australia materials in My Health Record and My Health App.

This partnership is set to significantly improve patient outcomes:

- Improved access to information: Patients will have better access to critical information through My Health Record, aiding informed decision-making and continuity of care.

- Enhanced patient engagement: By involving consumers in development, digital health solutions will be more tailored to their needs, leading to higher engagement and satisfaction.

- Proactive health management: Leveraging My Health Record and My Health App to improve screening program uptake and provide proactive health prompts, leading to earlier detection and treatment.

- Continuous improvement and safety: Managing common risks and ensuring clinical safety and quality indicators are recognised and analysed.

- Collaborative expertise: Combining the Agency's technical expertise with Cancer Australia's specialised knowledge to develop evidence-based guidelines and materials.

Overall, this partnership underscores our dedication to leveraging national digital health infrastructure to improve health outcomes and ensure our services are informed by real-world experiences from healthcare practitioners and consumers alike.

Clinical Governance Stewardship of Better and Faster Access

As the Clinical Reference Group for the Better and Faster Access to Pathology and Diagnostic Imaging program approaches its final meeting in December 2024, it is set to deliver its final advice to the Program Control Group. This advice will focus on the safe and effective implementation of the program.

The Agency, as the System Operator of My Health Record, will continue to support the Department of Health and Aged Care in ongoing stewardship of the clinical safety aspects of the program.

This will involve:

- Continuous monitoring and evaluation of system changes.

- Gathering and analysing clinical safety and consumer experience data.

- Implementing a proposed clinical governance stewardship and evaluation model.

This model, developed through stakeholder consultation and research, aims to ensure effective clinical governance and supports the responsible management of the program.

Providing National and International Leadership

C3.0 Clinical Governance in Digital Health Bytesize Webinar Series

From October to December 2024, the Agency will host three exciting webinars on clinical governance, focusing on the themes of connect, care and confidence. In partnership with the Commission, these webinars will feature presentations from leading digital health experts, innovators and service providers. We will showcase how effective clinical governance processes can be implemented across diverse services, making it a must-attend series for anyone interested in the field.

C3.0 Clinical Governance in Digital Health Summit 2025

Building on the success of the 2023 Clinical Governance Summit, we are thrilled to co-host with the Commission, a fully online Summit in February 2025. For this Summit, we will dive into the implications for clinical governance of recent technological advances such as GenAI. Expect to hear from leading national and international experts who will share their knowledge and perspectives.

Connect-a-thon

In May 2025, we are planning a hands-on workshop for service providers, innovators and safety and quality specialists. This practical event will demonstrate how to embed clinical governance practices throughout digital health products and services. Participants will receive hands-on guidance on developing clinical governance frameworks and creating secure, fit-for-purpose digital solutions.

Integration of Clinical Governance into Procurement and Delivery

The Agency is responsible for national infrastructure, systems, and programs that enable the access and sharing of consumer health information to assist health professionals in their clinical decision-making. If health information is temporarily unavailable, incorrect, or incomplete, it can lead to adverse health outcomes. With the Government's policy to share health information to My Health Record 'by default,' healthcare professionals and consumers will increasingly rely on these systems, making system reliability and stability crucial.

Given the complexity and significance of national infrastructure, we must manage the transition to future state architecture with extreme care to ensure clinical safety and continuity of service for all users.

To maintain the availability of national infrastructure and meet future user needs, we will integrate clinical governance expertise throughout the planning, procurement, and delivery phases of the Modernisation agenda. This includes:

- Embedding clinical safety considerations at all stages with guidance from our CGC.

- Utilising CSMS policies and guidelines to manage clinical safety across all projects, with input from clinical safety experts.

- Engaging clinical and consumer DHAs throughout project lifecycles to ensure safety and consumer perspectives are considered.

- Continuously managing and mitigating clinical risks through ongoing monitoring and informed decision-making.

- Prioritising and sequencing activities based on clinical safety to minimise risk and ensure service continuity.

This approach ensures that we recognise, report, and analyse clinical safety and quality indicators, drive continuous improvement and maintain high standards of care. By focusing on these principles, we aim to deliver safe, high-quality digital health services that meet the evolving needs of healthcare professionals and consumers.

Clinical Safety Management System

We are very excited for the launch of our updated CSMS by Q4 2024. The platform will serve as a central hub, providing access to essential clinical safety resources for Agency staff and the DHAs. The CSMS outlines our approach to ensuring clinical safety through a comprehensive set of policies, processes, guidelines, and procedures that integrate seamlessly with our governance, project, product, and release frameworks.

A new clinical safety product library will include detailed information on what is being delivered, including the clinical risk status of Agency digital health products. This significant milestone not only enhances our clinical safety maturity but also connects staff with valuable information. To support the implementation, we will conduct workshops and awareness sessions to help embed the CSMS across the Agency.

Glossary

Term		Description
ACTS	Aged Care Transfer Summary	A document that provides important health information when a person moves from an aged care setting to acute hospital care.
ASL	Active Script List	A digital list of a person's electronic prescriptions and computer-generated paper prescriptions, making it easier for healthcare providers to manage medications.
CG	Clinical Governance	A system that ensures healthcare services are safe, high-quality, and continuously improving. It involves leadership, accountability, and a culture of safety.
CGC	Clinical Governance Committee	An advisory body that ensures that clinical governance is actively observed, measurable, and foundational to the Agency's clinical safety, quality, and continuous improvement agenda.
CIMS	Clinical Incident Management Service	A service that manages and investigates incidents where patient safety might have been compromised, ensuring that lessons are learned to prevent future incidents.
CIMT	Clinical Incident Management Team	A team that responds to and manages clinical incidents, ensuring patient safety and proper handling of the situation.
COI	Community of Interest	A group of people who share a common interest in a specific topic, such as clinical governance in digital health, and come together to share knowledge and ideas.

the Commission	Australian Commission on Safety and Quality in Health Care	A national organisation that works to improve the safety and quality of healthcare in Australia.
CRG	Clinical Reference Group	A group of healthcare professionals and consumers who provide advice on clinical matters to ensure that healthcare services are safe and effective.
CSMS	Clinical Safety Management System	A system that helps identify and manage risks to patient safety in digital health products and services.
DHA	Digital Health Adviser	A person who provides expert advice based on their professional (clinical and non-clinical) or lived experience (consumer or carer) on digital health projects to ensure they are safe and effective.
DHIG	Digital Health Interest Group	An international group focused on sharing knowledge and best practices in digital health.
DoHAC	Department of Health and Aged Care	The Australian government department responsible for national health policies and programs.
EPMO	Enterprise Portfolio Management Office	A team that oversees and manages all the projects and programs within the Agency to ensure they align with strategic goals.
FHIR	Fast Healthcare Interoperability Resources	A standard for exchanging healthcare information electronically, making it easier for different systems to work together.
Framework	The Clinical Governance Framework for Digital Health	Refers to the Clinical Governance Framework for Digital Health, which outlines the principles and practices for ensuring safety and quality in digital health.
HIE	Health Information Exchange	A national infrastructure for electronic sharing of health-related information among different healthcare organisations.

HIPS	Healthcare Information Provider Service	A middleware software service that integrates hospital and laboratory systems with My Health Record and the Healthcare Identifiers Service.
HV	Health Viewer	A tool that displays health information, such as allergies and medical conditions, to healthcare providers.
MCV	Medical Conditions View	A feature in MHR that provides a view of a patient's medical conditions.
MOU	Memorandum of Understanding	An agreement between two or more parties outlining the terms and details of their cooperation.
PGPA	Public Governance, Performance and Accountability	A framework that ensures government agencies operate efficiently, effectively, and ethically.
PPED	Policy, Programs and Engagement Division	A division within the Agency.
RTPM	Real-Time Prescription Monitoring	A system that tracks prescriptions in real-time to prevent misuse and ensure patient safety.
SOP	Standard Operating Procedure	A set of step-by-step instructions to help workers carry out routine operations safely and efficiently.