Artificial Intelligence Governance Code

Medical Software Industry Association Limited & Medical Technology Association of Australia

1 December 2025

MTAA Medical Technology Association of Australia

MSIA Medical Software Industry Association

MinterEllison Consulting.

Contents

The Code

This is the Medical Software Industry Association (**MSIA**) and Medical Technology Association of Australia (**MTAA**) Artificial Intelligence Governance Code, Version 1, 1 December 2025 (the **Code**).

Purpose

MSIA represents providers of Health Software to the Australian market. The medical software industry enables better outcomes and efficiencies for all parties involved in healthcare.

MTAA is the peak association representing companies in the medical technology industry. MTAA aims to ensure the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better outcomes to the Australian community.

MSIA and MTAA have **jointly** developed the Code to set quality standards at the organisational level for Artificial Intelligence (**AI**) governance within organisations that use, develop, design, manufacture, sponsor, distribute, deploy and/or supply AI Systems (for use) in a Health Context, such as AI-enabled Health Software.

NOTE: This Code sets out standards for the governance of procurement, deployment and use of AI Systems at the **organisation level**, not the **product level**.

This Code **does not apply** to Medical Devices, which are regulated by the Therapeutic Goods Administration.

The Participant Organisation is responsible to ensure any Medical Device is properly registered on the Australian Register of Therapeutic Goods.

A strong Code signals to stakeholders that Participant Organisations agree to a minimum set of standards for organisational governance of AI Systems in a Health Context. A strong Code:

- provides greater confidence, trust and certainty in the AI-era;
- ensures governance standards are fit for the Health Software industry;
- promotes consistent, industry-wide responsible AI governance practices; and
- includes ongoing compliance mechanisms to ensure that accreditation to the Code has influence and value.

The entire Health Software and medical technology industry benefits when organisations govern AI Systems responsibly. This in turn provides benefits for health care providers and the Australian community. The industry standards outlined in the Code demonstrate the capability and willingness of the industry to self-regulate responsibly.

MSIA and MTAA are jointly responsible for oversight of the Code.

The Code has 4 sections, as set out below.

1. Signatories and Accredited Organisations

- ✓ Any MTAA and MSIA member can become a **Signatory** to the Code, confirming they endorse the contents of the Code.
- ✓ Any MTAA and MSIA member can also apply to be accredited to the Code, as an **Accredited Organisation**. To be accredited, the organisation must:
    - be a member of MSIA or MTAA; and
    - provide evidence they satisfy the Code as set out in the Artificial Intelligence Accreditation Standard.

  Accredited Organisations can display the MSIA or MTAA logo *as appropriate* with the text "Accredited Signatory to the MSIA & MTAA AI Code", to demonstrate to the market that they meet the industry standard for safe and responsible governance of AI Systems as set out in the Code.

For further details about how to become a member of the MSIA or MTAA, please refer to:

- MSIA Members page: Join the MSIA
- MTAA Members page: Benefits of Membership - MTAA

For the Code, any Accredited Organisation or Signatory is described as a **Participant Organisation**.

2. Scope and Application

✓ The Code is relevant for organisations that use, deploy, develop, design, manufacture, sponsor, distribute, implement and/or supply AI Systems (for use) in a Health Context, including AI-enabled Health Software.

⊗ The Code **does not** apply to the use, deployment, development, design, manufacture, sponsorship, distribution or implementation of any device or technology that is a Medical Device.

3. General Ethical Principles

The Code acknowledges the Australian Government's AI Ethics Principles as an important reference point for AI governance and draws on those principles in the General Ethical Principles below.

Each Participant Organisation will use, deploy, develop, design, manufacture, sponsor, distribute, implement and/or supply AI Systems (including Health Software that incorporates an AI System):

1. in a way that considers impacts and benefits on the individuals, society, and the environment, including by prioritising patient safety and the enhancement of patient care;
2. in a way that is respectful of human rights, dignity, and the autonomy of individuals;
3. in a way that is fair, inclusive, tested for, and equipped with, proportionate and appropriate bias and discrimination control measures;
4. in a way that aligns with applicable privacy laws in the relevant jurisdiction, and protects data security;
5. with appropriate systems, policies and processes for testing for safety, reliability, and operation (in accordance with intended purpose) in place;
6. in a way that promotes transparency and responsible disclosure to support consumers to understand when and how AI Systems engage with and impact them; and
7. in an accountable way, ensuring that those responsible for AI Systems are identifiable, and that appropriate human oversight is maintained.

4. Industry Code Criteria

1. Accountability

The Participant Organisation will establish and maintain appropriate processes to support organisation-wide accountability and regulatory compliance in the use of AI Systems. This may include (as is appropriate in the organisational context):

- appointing an overall owner for AI use;
- developing a clear AI strategy;
- developing a documented organisational AI governance framework; and
- ensuring that personnel (particularly executives) possess the appropriate knowledge and competencies to uphold quality and compliance in the governance and use of AI Systems.

Internal processes will be documented to demonstrate accountability across the Participant Organisation.

The Participant Organisation will take steps to put in place oversight of AI Systems throughout their lifecycle.

2. Risk Management

The Participant Organisation will establish and maintain appropriate risk-management processes to identify, assess and address risks associated with AI Systems across their lifecycle, proportionate to their organisational context.

Specific risk-management strategies will be implemented to manage clinical risk. This may include, for example, a requirement that:

- AI Systems are only applied in clinical practice, where clinically suitable;
- before deployment, any Health Software that incorporates an AI System undergoes appropriate clinical validation and approval (for instance to confirm that clinical expertise is leveraged throughout the total product life cycle, the Health Software incorporating an AI System uses datasets that are representative, and selected reference standards are fit-for-purpose); and
- after deployment, the AI System is subject to ongoing monitoring and review to ensure its performance and risk profile remain appropriate for a clinical context, and re-training risks are managed (where applicable).

If risks cannot be eliminated, reasonable steps will be taken to mitigate these risks.

To demonstrate compliance with risk management processes, the Participant Organisation may develop risk taxonomies, implement risk registers, develop and maintain quality management documentation, and attend to delineating responsibilities across the AI System supply chain.

3. Data Governance

The Participant Organisation will establish and maintain appropriate data governance, privacy and cybersecurity measures across the AI System lifecycle to:

- comply with applicable privacy laws, including the *Privacy Act 1988* (Cth) and any applicable State or Territory legislation binding on the Participant Organisation;
- safeguard the provenance, security and quality of the data stored, including its accuracy and currency;
- protect against unauthorised disclosure, use, and access to data by AI Systems (including when incorporated in Health Software); and
- ensure the quality of data, including its accuracy, currency and management across the data lifecycle,

as appropriate, having regard to the unique characteristics of any AI System in use and the Participant Organisation's position in the AI System supply chain.

4. Testing, Monitoring and Controls

The Participant Organisation will establish and maintain processes to test and evaluate AI Systems across the AI System lifecycle. The frequency and nature of testing and monitoring will be determined by the Participant Organisation, having regard to the nature and complexity of the AI System/s in use.

The Participant Organisation will implement proportionate controls to mitigate identified risks and will establish processes to facilitate transparency of AI Systems, enabling human oversight where appropriate, through a high-level understanding of AI System behaviour, and the ability to correct or amend outputs where necessary.

To support this, the Participant Organisation will ensure that workplace AI System use policies are developed and implemented to guide personnel on the safe and compliant use of AI Systems within the Participant Organisation.

To the extent the Participant Organisation develops Health Software incorporating AI Systems, that Participant Organisation acknowledges:

- Health Software incorporating AI Systems must be proven to an appropriate standard of evidence and deemed safe for the population in the Health Context in which they are intended to be applied. The level

of evidence required to demonstrate the efficacy, accuracy and safety of Health Software incorporating an AI System should be commensurate with the level of risk connected to the use of that AI System; and

- the importance of post-market surveillance systems, including to manage any re-training risks.

5. Inform End Users

The Participant Organisation will ensure that end users can reasonably access relevant information about the AI Systems used and developed by the Participant Organisation, particularly where outputs may significantly or materially affect individuals' rights or interests.

6. Contestability

The Participant Organisation will establish mechanisms that enable and support individual people directly, significantly and materially impacted by an AI System used by the Participant Organisation to challenge how that AI System is being used, and contest AI System decisions, outcomes, or interactions.

7. Transparency

To the extent the Participant Organisation develops or sells AI Systems (including Health Software incorporating an AI System), that Participant Organisation will ensure that each AI System is labelled with a version number, and that AI System is supplied to third parties (including users) with access to information regarding the particular AI System:

- in an accessible way; and
- to assist users to effectively address potential risks arising from the use of that AI System.

The Participant Organisation will ensure users can reasonably access relevant information about each AI System developed, or deployed by the Participant Organisation, for use in a Health Context, including:

- the particular AI System's intended use and purpose and indications for use, benefits and risks, and its regulatory status (i.e. it is not a Medical Device);
- general information about the dataset on which the AI System was (and is) tested and trained, including the extent to which customer data has been used to train and/or improve that system;
- the role of human oversight and supervision required for the safe deployment of the AI System;
- limitations of the AI System, including any Health Contexts in which it should not be used, and the Participant Organisation must consider whether disclaimers are appropriate in the AI System user interface, ensuring to take reasonable steps to reduce risk of alert-fatigue;
- the type of AI approach or AI technology used (for example, rule-based systems, machine learning models, or generative methods); and
- how to address system failures.

8. Record Keeping

To the extent it is within the Participant Organisation's control, the Participant Organisation will ensure that appropriate records are made and kept in relation to AI System use, deployment, development, design, manufacture, sponsorship, distribution or implementation by the Participant Organisation.

9. Stakeholder Engagement

The Participant Organisation will, at its discretion, take reasonable steps to actively engage with stakeholders (which may include, for example, the Therapeutic Goods Administration, Royal Australian College of General Practitioners, Pharmacy Guild Australia, Royal Australasian College of Physicians, Australian Medical Association, Royal Australasian College of Surgeons, Royal Australian and New Zealand College of Anaesthetists, Royal Australian and New Zealand College of Radiologists, Australian Health Practitioner Regulation Agency, Department of Health, Disability and Ageing, Australian Digital Health Agency, Australian Alliance for Artificial Intelligence in Healthcare, Australian Patients Association, Hospital peak bodies, local and government health organisations) throughout the AI System lifecycle, supporting the identification of potential harms and unintended consequences of AI System use, deployment, development,

design, manufacture, sponsorship, distribution or implementation by the Participant Organisation and shape the ethical and inclusive design of AI System solutions. The Participant Organisation will implement measures to detect and minimise unwanted bias, promote accessibility, and remove ethical prejudices, striving for continuous improvement and alignment with the General Ethical Principles, while supporting the Participant Organisation's broader organisational objectives.

10. Procurement and implementation of AI Systems

When procuring, using and deploying AI, the Participant Organisation will act in accordance with the General Ethical Principles and Criteria 1 – 9 of the Code.

Defined Terms

Accredited Organisation means an MSIA Member or MTAA Member accredited to the Code.

AI System means a machine-based system that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments. Different AI Systems vary in their levels of autonomy and adaptiveness after deployment, but excludes all Medical Devices.

General Ethical Principles means those principles set out in part 3 of the Code.

Health Context means in the context of providing health care, aged care and disability care (including health care to other vulnerable populations, such as mental health care and health care provided to indigenous people), and includes any clinical or related ancillary services, such as related administrative processes.

Health Software means software that is used in a Health Context, but excludes all Medical Devices.

Medical Device has the meaning given in section 41BD of the *Therapeutic Goods Act 1989* (Cth), which includes any software intended to be used for a therapeutic purpose, such as diagnosis, prevention, prediction, prognosis, and treatment of a disease, injury, or disability.

MSIA means the Medical Software Industry Association Ltd (ABN 82 324 598 961).

MTAA means the Medical Technology Association of Australia Limited (ABN 61 129 334 354).

Participant Organisation means an MSIA or MTAA member who is a **Signatory** to the Code, or an **Accredited Organisation**.

TGA means the Therapeutic Goods Administration.

General Reference Material Links

IMDRF AIML WG GMLP N88 Final

Voluntary AI Safety Standard | Department of Industry Science and Resources

Guidance on privacy and the use of commercially available AI products | OAIC

Guidance on privacy and developing and training generative AI models | OAIC

ISO/IEC 42001:2023 - AI management systems

AI Risk Management Framework | NIST

Therapeutic Goods Act 1989 - Federal Register of Legislation

Privacy Act 1988 - Federal Register of Legislation

MSIA Code of Practice

Code of Practice - MTAA

Australia's AI Ethics Principles | Australia's Artificial Intelligence Ethics Principles | Department of Industry Science and Resources

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