

Technology Strategy Branch  
Department of Industry, Science and Resources  
Australian Government  
Via: [DigitalEconomy@industry.gov.au](mailto:DigitalEconomy@industry.gov.au)  
Canberra ACT 2600

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## **Roche Submission to Supporting Responsible AI: Discussion Paper**

To Whom It May Concern,

Roche welcomes the opportunity to provide a submission to the Department of Industry, Science and Resources Discussion Paper on Safe and Responsible AI in Australia. Roche supports the Australian Government's ambitions to be a leader in the responsible use of Artificial Intelligence (AI), and the process of consultation by seeking broad advice on the steps the Government can take to mitigate the potential risks.

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics, as well as growing capabilities in the area of data-driven medical insights, help Roche deliver truly personalised healthcare. Roche is working with partners across the healthcare sector to provide the best care for each person.

Central to Roche's strategy is a focus on personalised healthcare, which is a shift from one-size-fits-all approach to disease, to maintaining health throughout one's life by applying the right health interventions for the right person at the right time. To enable personalised healthcare, Roche is developing and partnering on digital health solutions like AI, which will deliver the benefits to Australian patients, providers, and the health system as a whole.

Roche is uniquely positioned to apply AI and Machine Learning (ML) to dramatically accelerate and transform our research into the development of new therapeutics, diagnostics, and treatments. At Roche, we work alongside some of the largest datasets and data generation capabilities, which our scientists use to train and optimise ML algorithms to glean new insights.

This is for targeting drug discovery, answering fundamental questions about human biology and disease, and creating a 'lab-in-a-loop'. This is where experimental data feeds computational models that make new, experimentally testable predictions allowing for iterative development of better therapies, including tackling targets and diseases that we could not previously address.<sup>1</sup>

Over a patient's journey with the health system thousands of data points are created, and these data will help identify changes in their health and enable tracking of similar patient groups across institutions and

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<sup>1</sup> Roche data on file

geographies. Through AI and ML, this will eventually allow for comparison of outcomes as well as predictive measures.<sup>2</sup>

Our digital solution for pathology now delivers high-resolution digital images of tissue samples even faster as the evaluation is not carried out using a microscope, but electronically. AI makes it easier to diagnose cancer and enables more targeted and effective treatment for the patient concerned.<sup>3</sup>

Concerns about the sustainability of healthcare spending can include inefficiencies at the point of care, to the rising cost of innovative treatments, to the inadequacy of end-of-life care. Roche would contest that there needs to be a more precise, evidence-based, holistic approach to health that is tailored to individuals, helps patients achieve better outcomes, and can be sustained over the long term through increased system efficiency. AI based solutions have the potential to support healthcare to become more efficient, through personalising healthcare.

While the Discussion Paper is looking to identify potential gaps in the existing domestic governance landscape, it must not lose sight of the enormous patient benefit that this new technology can bring. Roche believes that any new governance mechanisms must take a balanced approach to the potential risks and benefits of the use of this new technology.

Roche has provided feedback to specific questions presented in the Discussion Paper below.

**Question 4. Do you have any suggestions on coordination of AI governance across government? Please outline the goals that any coordination mechanisms could achieve and how they could influence the development and uptake of AI in Australia.**

Roche believes it is vital to consider AI governance and coordination across jurisdictions, and agrees with the Productivity Commission that greater coordination between policymakers and regulators on diverse, complex, and quickly evolving technologies will help avoid a piecemeal regulatory environment, and avoid barriers for adoption.<sup>4</sup>

At Roche, our aim is to increase AI and ML's utility for better development of medical treatments which could ultimately improve outcomes for patients, and improve health system efficiencies. To avoid barriers for adoption and fragmented approaches to these technologies, it is essential to include a goal around federal coordination of governance for data sharing and access, supported by federal funding, that will enable greater use and uptake of AI across Australia.

Roche strongly supported the strong investment seen globally during the pandemic response to prioritise the creation of platforms for interoperability for the future and society, and to understand cross-border data sharing. High-quality datasets are essential to the application of AI and ML, and Roche believes this investment must continue and be expanded in Australia, and that it is important for the Federal Government to lead a nationally coordinated approach.

Learning from the COVID-19 pandemic, it is time to work towards dynamic data ecosystems which are interoperable, high quality, respect data privacy and ethics, and enable use as a public good. While the *Data Availability and Transparency Act 2022* is a positive first step for sharing Australian Government

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<sup>2</sup> Roche Annual Report 2022

<sup>3</sup> Roche Annual Report 2022

<sup>4</sup> Department of Industry, Science and Resources 2023. Safe and Responsible AI in Australia: Discussion Paper

data<sup>5</sup>, a broader perspective (including greater use of Real World Data (RWD)) should be considered as a goal that will influence the uptake of AI.

### **Question 11. What initiatives or government action can increase public trust in AI deployment to encourage more people to use AI?**

Roche believes that the Government can and should play a central and leading role in increasing the public trust of AI, as the Government is a highly trusted institution in Australia, and the Government has the ability to provide far-reaching credible information to its citizens. In particular, there is a real opportunity for the Government to highlight the public health benefit and the increased health system efficiencies if the adoption of these technologies is executed in an appropriate manner, with the right safeguards in place.

Additionally, there needs to be a coordinated effort to upskill and educate all stakeholders along the healthcare value chain, so that these stakeholders can support the Government's efforts to provide credible information to the general public. To do this successfully, there will need to be tangible and measurable examples of what the benefits will be, while acknowledging the steps the Government is taking to mitigate the risks.

Additionally, Roche would strongly support a Government-led campaign to update Australian's understanding of data literacy. As the use of AI and ML is inextricably linked to data policy, it may be very difficult for the general public to understand why their data is so important, how it may be used, what it would be used for, and the benefits to society. Lack of understanding and confusion can lead to trust issues.

The private sector can also play a role in increasing the public trust through demonstrating the benefits that they can bring to the public, and through the involvement in groups and partnerships for the ethical use of AI (i.e. AI for social good such as preventative medicine as well as disease diagnosis and treatment optimisation).<sup>6</sup> Roche has already developed an internal mechanism to oversee responsible oversight in the use of AI at Roche to help set the standard for the appropriate deployment of AI-powered technologies in healthcare.<sup>7</sup>

### **16. Is a risk-based approach better suited to some sectors, AI applications or organisations than others based on organisation size, AI maturity and resources?**

Roche notes that Box 4 within the consultation document outlines a potential risk management approach for AI. Of note is that medical surgery is listed as high-risk, which means that a greater level of management requirements and obligations are required for that activity.

Roche agrees that a risk-based approach is highly appropriate in the healthcare sector where there may be potential risks of patient harm that could result from AI misuse or negligence. This high-risk mitigation approach is already the case for a number of health services in Australia, which are

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<sup>5</sup> Office of the National Data Commissioner, 2022. Data Availability and Transparency Act 2022. Viewed 25 July 2023: <https://www.datacommissioner.gov.au/law/dat-act>

<sup>6</sup> Morgenstern, D & Neteanel Choman, E, Hasharon, H, 2023. LungFlag, a machine-learning (ML) personalized tool for assessing lung cancer risk in a community setting, to evaluate performance in flagging non-small cell lung cancer (NSCLC) regardless of sex or race. Journal of Clinical Oncology, Meeting Abstract, 2023 ASCO Annual Meeting 1.

<sup>7</sup> Roche data on file

constantly undergoing rigorous processes to ensure that Australian patients are safe, and this includes a meticulous process for assessing medicines and medical devices (including ‘software as a medical device’ (SaMD)) for registration and reimbursement.

The speed of innovation in the sector is moving at a rapid pace and regulators and policymakers need to ensure that the policy frameworks are flexible and adaptable to technological change. For example, ML is essential to research and development because the life sciences field is generating more data now than ever before, and ML algorithms are needed to parse large amounts of data to help find patterns that are challenging for human experts to identify.<sup>8</sup>

While this use of AI may be considered high-risk, Roche does not believe that additional regulatory requirements are required beyond what is already regulated by the *Therapeutic Goods Act 1989*, as well as the risk-based approach already applied by the Therapeutic Goods Administration.<sup>9</sup> Additional regulation for the use of AI in the health sector beyond the current requirements may become duplicative and burdensome, and could result in a delay in the advancement or the introduction of new technologies.

To complement the current regulations, private sector companies such as Roche are already applying voluntary ethical principles and standards in research, including the use of AI. Roche assesses the potential risks that may result from the use of AI systems and takes measures to mitigate the risks during both the development and deployment of AI applications<sup>10</sup>, which is in strong alignment to the risk management table provided in Box 4.

Examples that Roche employs include:

- Ensuring that there is a human-in-the-loop to make final decisions on any AI recommendations.
- Regular checkpoints to ensure that the AI avoids and minimises bias while maximising fairness.
- Robust testing over wide-ranging test datasets to build confidence that the AI does not introduce additional harms and ensuring that data used in training the AI cannot be identified to an individual patient.
- Consideration of security during the design and development of AI systems.

For the healthcare sector, Roche would support Government guidance and encouragement to healthcare companies to follow these principles and include them in internal risk-management requirements.

## Conclusion

Roche has 125 years of providing safe, trusted healthcare solutions, as we have done this within a framework that considers ethical, environmental, social, and governance implications to ensure maximum benefits for patients and society. We have the precedent and capacity to do the same in the area of data, advanced analytics, and AI and ML.

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<sup>8</sup> Roche data on file

<sup>9</sup> Therapeutic Good Administration, 2023. Product regulation according to risk. Viewed 26 July 2023: <https://www.tga.gov.au/product-regulation-according-risk>

<sup>10</sup> Roche data on file

Roche appreciates the opportunity to provide this feedback to the Discussion Paper and looks forward to hearing further developments in this area. If you have any further questions about this submission please contact Mark Stewart, Policy and Value Partner on 0438 653 623, or at [Mark.Stewart.MS1@Roche.com](mailto:Mark.Stewart.MS1@Roche.com).

Yours faithfully,

A handwritten signature in blue ink, appearing to read "Stuart Knight".

Stuart Knight  
General manager  
Roche Products Pty Limited  
Gadigal Country  
Level 8, 30-34 Hickson Road, Sydney NSW 2000  
Australia