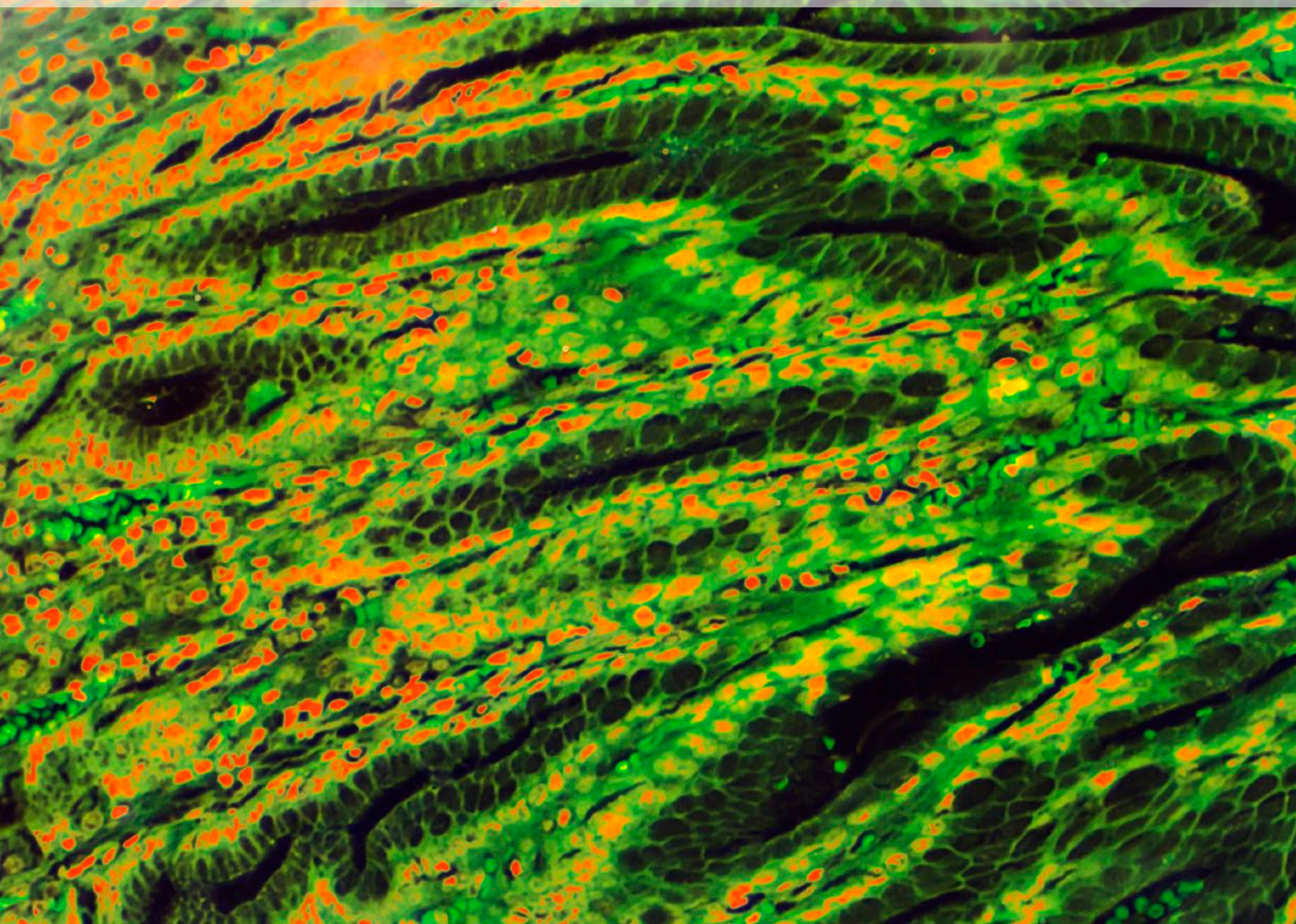
Australia's National
Science Agency

Non-animal models

A strategy for maturing Australia's medical product development capabilities

Executive summary | 2023



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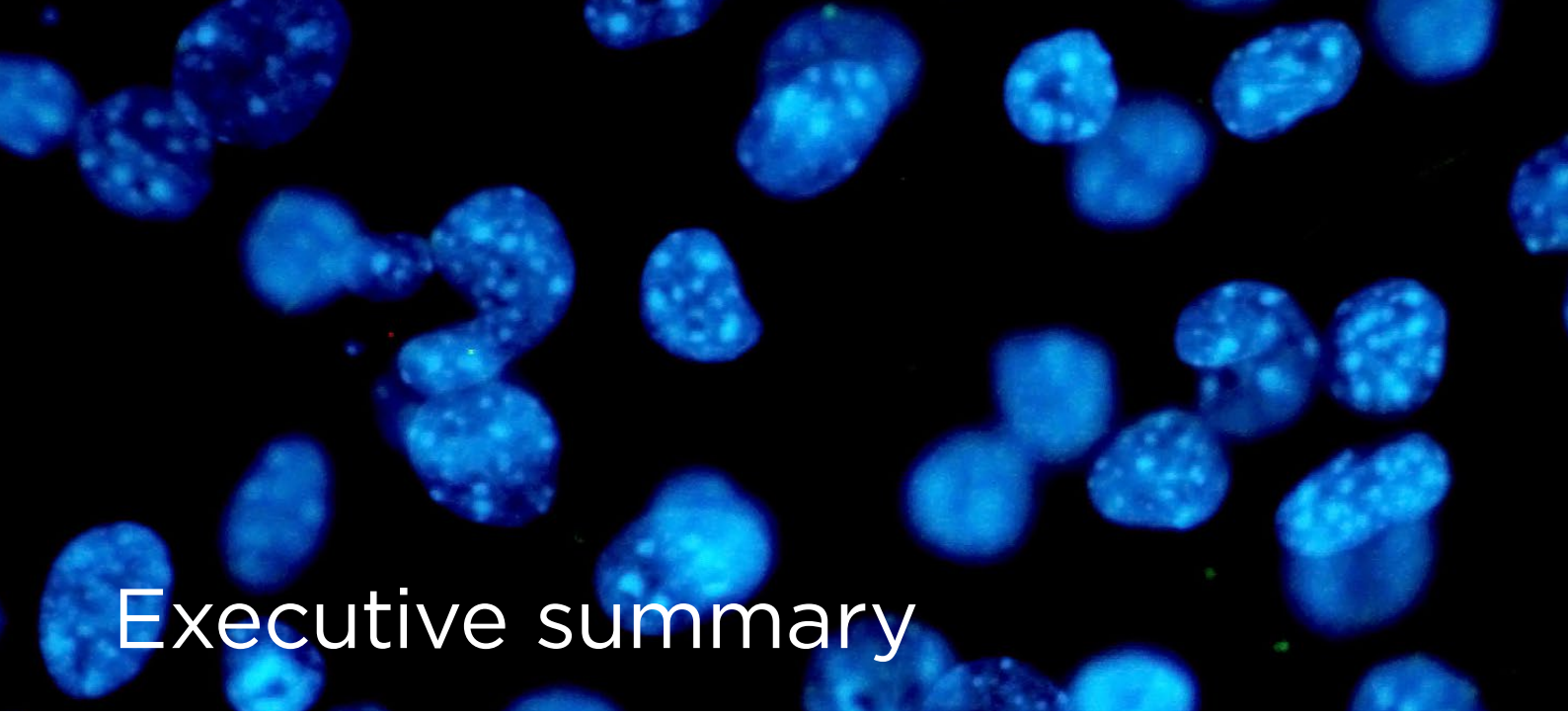


Executive summary

This report assesses the potential of emerging non-animal models to complement or replace traditional approaches in medical product development over the next 15 years. The analysis includes specific opportunities and recommendations for Australia to strategically enhance capability in this field, improve research quality and productivity, strengthen sovereign capability, and generate new national revenue streams.

The report defines non-animal models as biological models that use human-derived or humanised cells, tissues or data. While the scope of this analysis is restricted to non-animal model applications across the medical product development process, the report's recommendations could benefit applications in other fields, such as veterinary and agricultural medicines, cosmetic testing, and eco-toxicology.

The report was informed by consultation with **103** individuals from **66** organisations across industry, research and government.

Why non-animal models?

The complexity of non-animal models is rapidly increasing, equating to or surpassing the performance of traditionally used animal models in several applications. Due to their enhanced biological relevance, non-animal models can increase productivity and reduce costs by identifying unsuitable medical products earlier in development and re-investing savings in more promising candidates. These models also support broader global '3Rs' objectives to replace, reduce and refine the use of animals for research and testing purposes.

Why now?

Recent policy shifts in the United States and Europe encourage the transition away from animal use. These shifts are likely to support the already strong growth in the global non-animal testing market, valued at USD 1.11 billion in 2019, and expected to grow at a compound annual growth rate of 10.4% during 2019–2025. At the same time, animal model supply chains face increased risks, prompting alternative approaches to become more valuable.

Why Australia?

Australia has comparative global strengths in non-animal models for several organ systems likely to disrupt the status quo about the use of animal models over the next 15 years, including cardiovascular, respiratory, and nervous systems. Australia also possesses key foundational capabilities, including existing infrastructure (the National Collaborative Research Infrastructure Strategy – NCRIS – network), high throughput screening capabilities, and internationally recognised capacity for induced pluripotent stem cell generation, a key input for non-animal model development. These emerging models will also be critical to protect and further strengthen Australia's $1.4 billion clinical trials sector.

Australia must act now to secure a key role in this emerging capability.

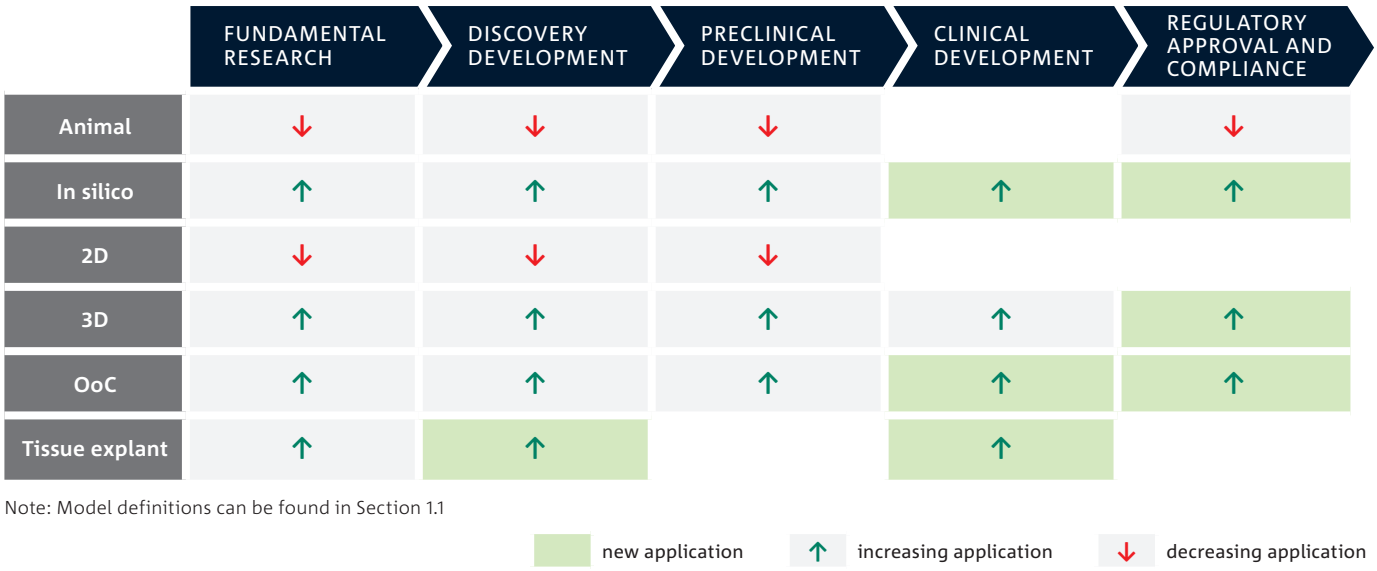
Despite relevant research and infrastructure strengths, Australia is still maturing and coordinating these national capabilities. This report seeks to support these coordination efforts. It discusses how Australia can accelerate non-animal model applications' demonstration, scaling, and commercial success.

The next 15 years will see an increase in the use of non-animal models across all stages of the medical product development process.

The most significant growth is likely to come from complex in vitro models such as organoids (3D) (estimated **$1.28 billion in revenue** for Australia by 2040) and organ-on-chip (OoC) technologies (**$310 million in revenue**).[1] In silico models are also anticipated to be more widely applied throughout the development process; used in conjunction with in vitro models to complement and validate findings. Figure 1 summarises the expected shifts in non-animal model use across stages of the medical product development process.

The organ systems most likely to see non-animal models replace the status quo include cardiovascular, respiratory, gastrointestinal, skin, eye, and liver.

Figure 1. Expected shifts in the use of models for medical product development



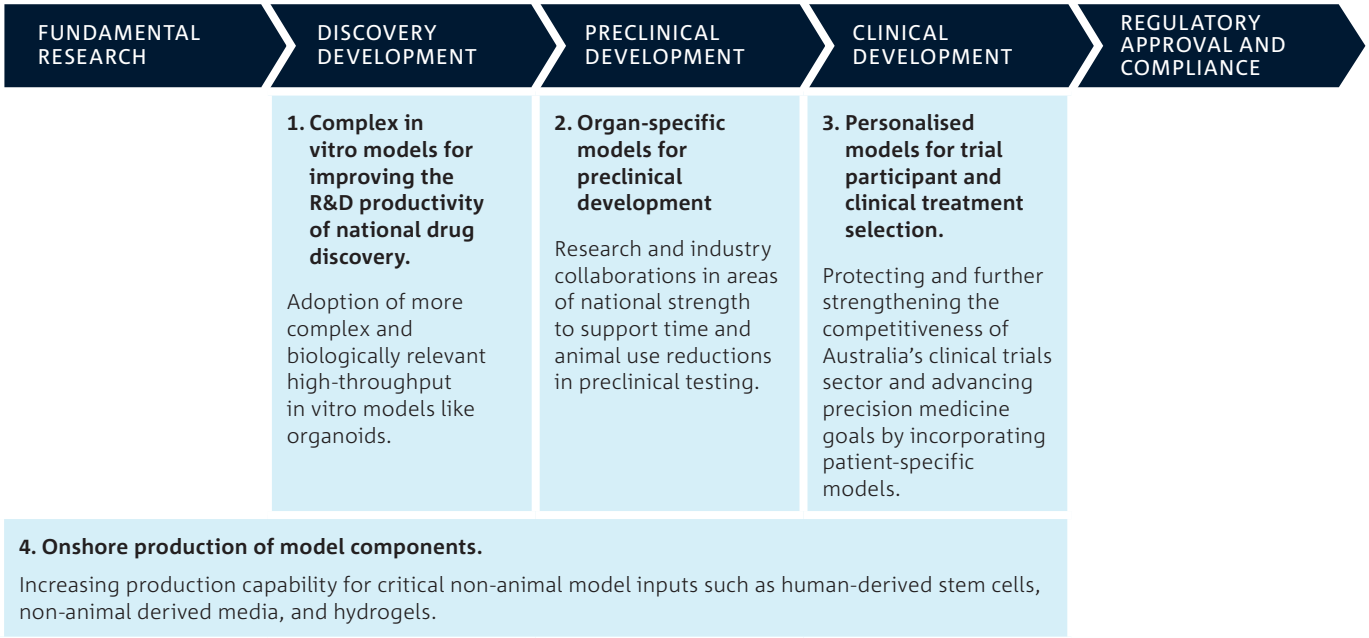
Note: Model definitions can be found in Section 1.1

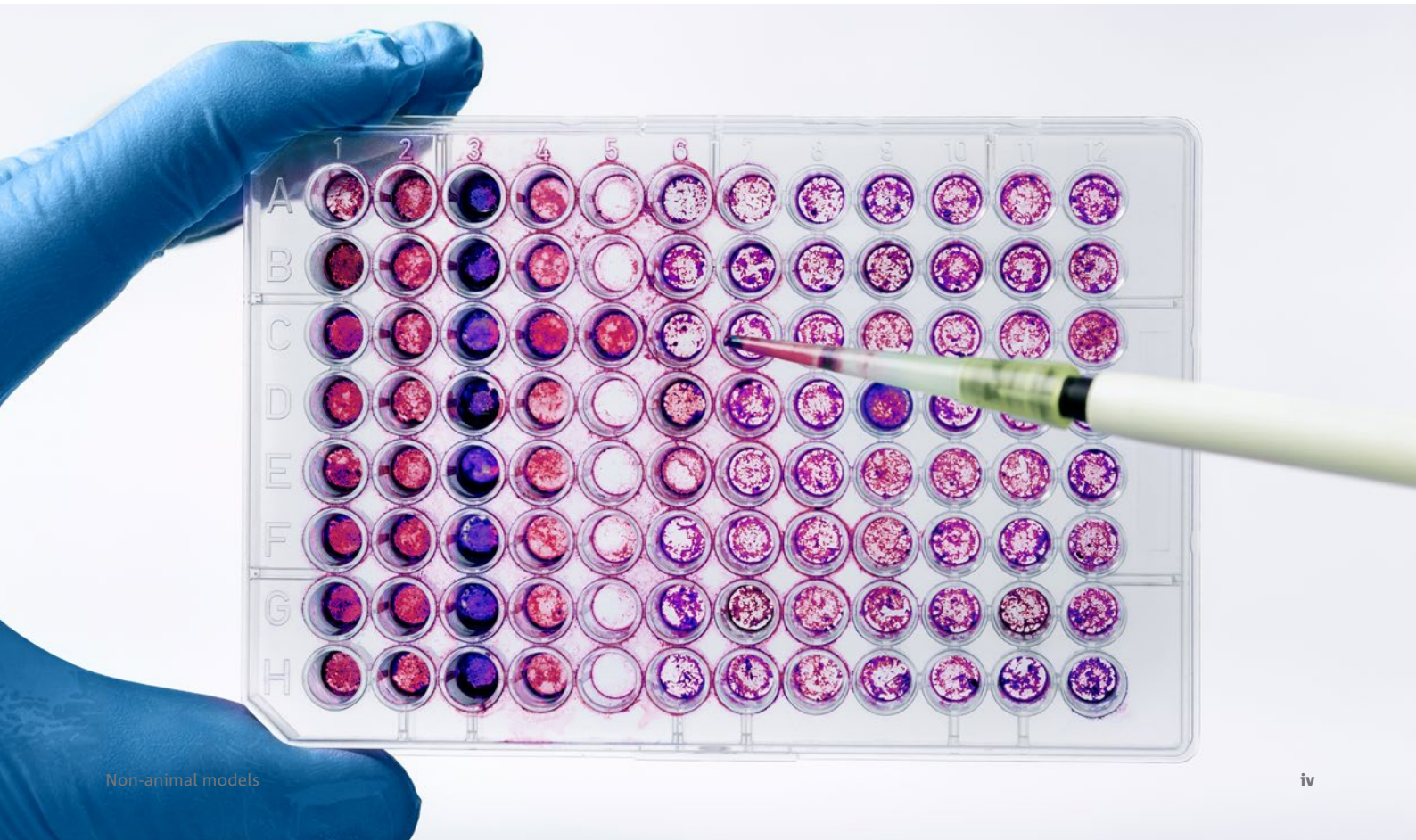
1 Based on CSIRO Futures economic analysis of global non-animal model market size data, Australian share of global publications by model and national wage data. See Appendix A.5 for the methodology used.

Four national opportunities pair Australian strengths with global needs.

Developing and applying non-animal models within these settings (Figure 2) can benefit the quality of domestic research and development (R&D) activities or create revenue streams for non-animal model applications by providing global services and partnerships.

Figure 2. Four national opportunities





Ten recommendations to provide Australia with the foundation to pursue these opportunities.

While the opportunities were developed considering a 15-year time horizon, setting Australia on a path towards these opportunities would require actioning the recommendations within five years. Within these five years, recommendations can be grouped and ordered by themes, with those aimed at coordinating and updating existing processes considered the most important first steps by those consulted (Figure 3). These activities would set a strong foundation for the remaining recommendations, which aim to integrate local capabilities into medical product development before strengthening production and commercialisation. Recommendations for non-animal model validation data will provide the evidence base to generate momentum across all themes. More discrete R&D priorities, actioned in parallel to recommendations, will act as supporting cross-cutting activities to strengthen Australia's non-animal models' capabilities further.

Figure 3. Recommendations and R&D priorities

Coordinate and update existing processes

1. Establish a national consortium that coordinates and promotes Australia's non-animal model capabilities
2. Develop national data collection standards on the use of animals in scientific research, teaching and testing
3. Align TGA processes and industry guidance with new FDA procedures for accepting non-animal model data

Integrate local capabilities

4. Develop a national biobanking and tissue collection network
5. Integrate outputs from NCRIS platforms into a coordinated pipeline for non-animal models

Strengthen production and commercialisation

6. Facilitate IP management and material access for research and industry collaborations
7. Enhance commercial skillsets across the non-animal model sector
8. Update biomedical R&D infrastructure to support non-animal model capabilities

Validation data

9. Conduct retrospective studies that compare animal and non-animal model predictivity
10. Conduct systematic reviews of locally and internationally developed non-animal models

R&D priorities

- Support the economic case for non-animal models in medical product development
- Improve analytics for increasingly complex in vitro models
- Advance the quality of model inputs and hardware
- Extend the capabilities of in vitro models for a closer recreation of human physiology across healthy and diseased states

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