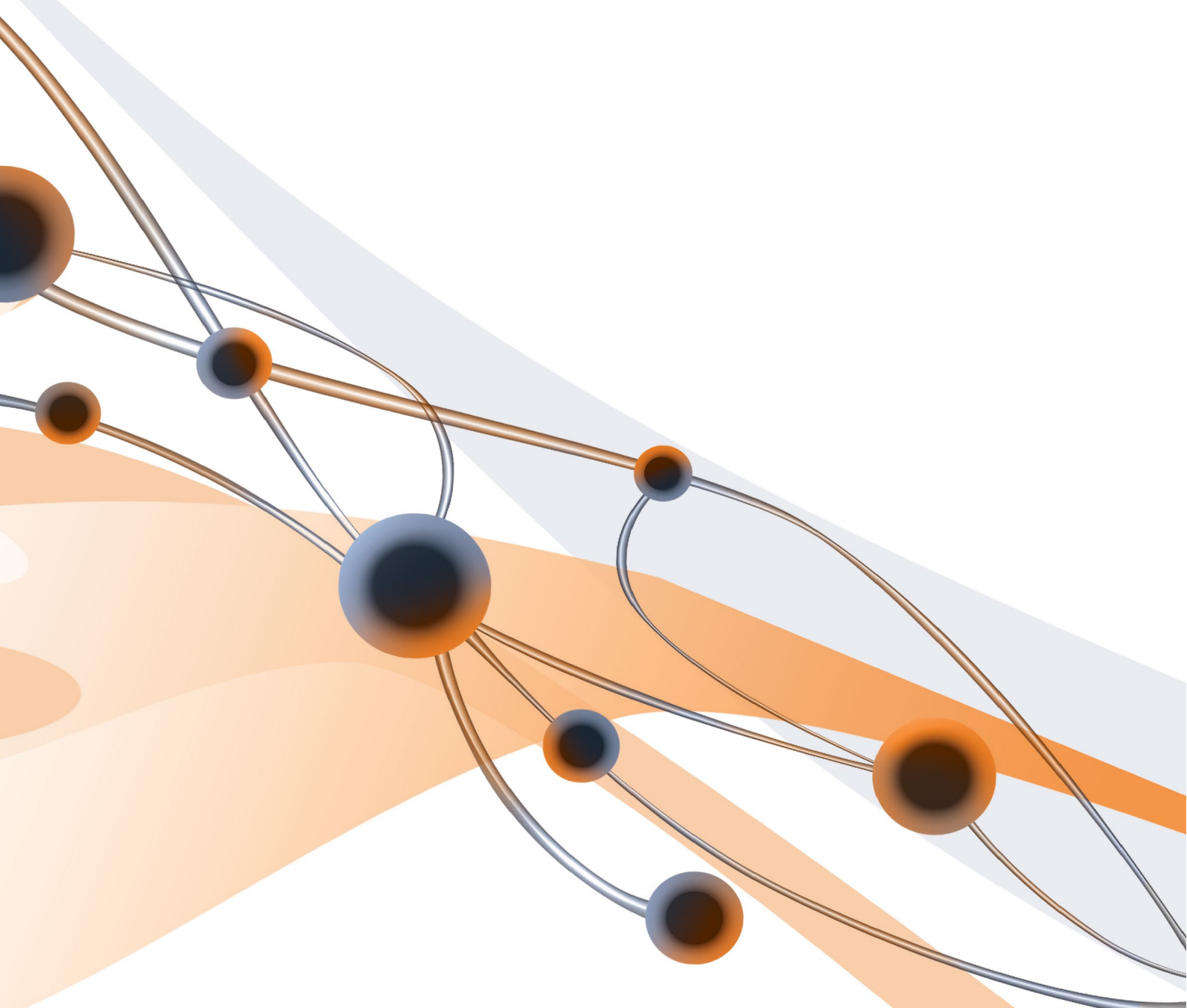


Better targeting the Research and Development Tax Incentive – exposure draft legislation

Research Australia Submission

An abstract graphic featuring a network of interconnected nodes and lines. The nodes are represented by spheres of varying sizes, some in shades of blue and others in shades of orange. They are connected by thin, curved lines that create a sense of movement and flow. The background consists of broad, sweeping bands of light orange and light blue, which intersect and overlap, creating a dynamic and modern aesthetic.

**RESEARCH
AUSTRALIA**

*Championing
Australian health
& medical research
& innovation*

About Research Australia

Research Australia is the national peak body for health and medical research and innovation (HMR), representing organisations across the full research and innovation ecosystem. We provide national leadership to shape the policy agenda, mobilise the sector around shared priorities, drive evidence-based solutions to system-wide challenges, and build public and political recognition of the value and impact of HMR. Our work is focused through four advocacy platforms: Smarter Investment and Value Realisation, Health Innovation, A Supported and Diverse Research-Active Workforce and Equity.

Executive Summary

Research Australia supports the objective of ensuring the Research and Development Tax Incentive (R&DTI) is effective, sustainable and drives additional business investment in R&D. However, reforms must be designed carefully to avoid reducing investment in precisely those areas where the R&DTI has the greatest impact. This is particularly important for HMR, where development pathways are long, capital intensive and highly regulated, and companies can remain pre-revenue for many years while progressing through clinical validation, trials and regulatory approval.

Research Australia has consistently recognised the R&DTI as a critical component of Australia's innovation system. In our 2020 submission to the Senate Economics Legislation Committee, we highlighted evidence that additionality is particularly high among small firms and start-ups undertaking biological and medical R&D, where refundable R&DTI payments provide critical cash flow that enables research to continue. We also highlighted the significant spillover benefits associated with clinical research, including earlier patient access to new products and treatments, regulatory benefits, employment, skills development and broader growth in Australia's health innovation sector.

These principles remain directly relevant to the current exposure draft. Research Australia welcomes recognition that biotechnology and medical technology companies have distinct development pathways, including through the proposed extension of the refundable offset from 10 to up to 15 years for eligible firms undertaking R&D related to therapeutic goods. However, several aspects of the reforms could undermine the effectiveness of this recognition. This is consistent with Research Australia's longstanding concern that the refundable R&DTI is particularly important to early-stage research-intensive companies precisely because they can operate at a loss for several years while developing products for market. The 15-year extension is therefore important, but it must adequately reflect the full range and duration of health innovation pathways.

Research Australia is also concerned that the proposed start-day provisions could disadvantage university spinouts. Australia's universities and research institutes are important sources of discoveries that are subsequently translated and commercialised through new companies. A spinout should not effectively be "born old" because its relationship with, or ownership by, an established university results in the age of the founding institution being relevant to determining the company's refundability period. The legislation should provide certainty that the refundability window reflects the age and commercial development pathway of the new venture itself. This would better align the R&DTI with the Government's broader objective of translating Australian research into new products, companies and industries.

Finally, Research Australia is concerned about the proposed removal of supporting R&D activities from eligibility, notwithstanding the proposed increase in offsets for eligible core R&D. Health and medical R&D does not occur as an isolated experimental activity. Clinical

validation and clinical trials depend on interconnected activities including study preparation and monitoring, manufacture of investigational devices or products, data management and analysis, regulatory processes and other activities necessary to conduct the research. Research Australia raised similar concerns in 2020 about attempts to distinguish clinical trial expenditure from related activities, noting the practical difficulty of separating the trial itself from essential preparatory, administrative and associated expenditure. Where supporting activities are directly related and necessary to the conduct of eligible core R&D, their wholesale exclusion risks narrowing support for the very translation pathway the R&DTI is intended to encourage.

Research Australia therefore recommends that the final reforms preserve effective refundable support across the realistic development timeframe for HMR companies; ensure university spinouts receive an appropriate refundability period based on the new venture rather than the age of the originating institution; and retain eligibility for supporting activities that are directly related and necessary to eligible core R&D. More broadly, the impact of these changes on additionality, and commercialisation should be assessed carefully to ensure the reforms strengthen, rather than inadvertently constrain, Australia's capacity to translate HMR into products, companies, jobs and improved health outcomes.

Why The Incentive Matters for HMR

Australia's HMR sector is economically generative and supports productivity, sovereign capability, skilled employment and better health outcomes. Research Australia has previously highlighted that every dollar invested in HMR returns around four dollars to the Australian economy¹, with HMR representing around a quarter of national R&D activity.²

Australia now invests approximately 1.7% of GDP in R&D, far below the OECD average of 2.72%. That figure has been shrinking since it peaked at 2.24% in 2009. Science & Technology Australia has pointed out that R&D investment has not kept up with inflation for more than two decades³. A key gap in this is business investment. Business expenditure on R&D was 0.93% of GDP in 2023-24, unchanged since 2017-18. This is less than half the OECD average, which sits at 1.99%. It is clear that more needs to be done. As Research Australia has previously highlighted:

While there are signs that Australia is becoming more innovative, a concerted long-term investment in innovation by the Government and the private sector is required over decades if we are to see innovation have a real impact on our exports and permeate our economy. The R&DTI Scheme provides an excellent mechanism for market forces to determine where and how R&D investment dollars should be invested. It has been highly effective at allocating scarce investment into areas where Australia and its research community have strengths, particularly in health and medical research and innovation. The R&DTI Scheme is a more effective and predictable system for incentivising investment in small and large businesses than other mechanisms such as grant schemes, which are less predictable and tend to be

¹ KPMG, Economic Impact of Medical Research in Australia (2018); Research Australia, Pre-Budget Submission 2026–27 (January 2026), p 2.

² Research Australia, Response to the Productivity Commission's Five Pillars of Productivity Inquiries Interim Reports (September 2025), p 10.

³ Science and Technology Australia; Policy Submission: Select Senate Inquiry into Productivity in Australia (February 2026), p 2.

targeted to deliver a specific policy outcome, rather than encouraging market led investment⁴.

Tax incentives such as the R&DTI must therefore be retained as vital components of Australia's need to increase investment in R&D, encourage economic diversification and improve productivity.

Recommendations

1. **Remove the 15-year company-age limit.** Eligibility should instead turn on whether the company is genuinely innovative, below the turnover threshold and still undertaking or commercialising qualifying innovation.
2. **The therapeutic goods test must reflect how modern health technologies are developed,** not only the final regulated product.
3. **Supporting R&D activities should be retained,** the cost of manufacturing for clinical trials should also remain eligible.
4. **Protect genuine spinouts.** A university, hospital, medical research institute or other research organisation should not set the spinout's start date, aggregate its turnover with the spinout merely because it is a substantial shareholder, or cause pre-incorporation research to exhaust the spinout's eligibility period.
5. **Provide certainty at the point of investment.** Introduce an accessible binding determination or safe-harbour process, supported by objective indicators such as patents, competitive innovation grants, ethics approval, entry into a recognised regulatory pathway, or registration of eligible R&D activities.
6. **Coordinate the Innovative Businesses CGT Concession with the R&DTI and venture-capital settings.** Definitions and administration should be aligned to avoid contradictory outcomes and unnecessary compliance costs.

1. The 15-year limit remains too short

The draft's move to increase the company age limit for the refundable offset from 10 to 15 years for R&D on therapeutic goods is a welcome, but Research Australia maintains that lifting this cap completely is the more preferred outcome. Across the life sciences sector, the period from incorporation to a significant liquidity event may include prototype development, pre-clinical work, ethics approval, clinical validation, regulatory approval in Australia and overseas, reimbursement assessment, manufacturing scale-up and procurement. These activities often occur sequentially, depend on external approvals and require multiple capital rounds.

A hard age cap withdraws the incentive precisely when a long-cycle company may need later-stage capital most. It can also create arbitrary differences between companies pursuing comparable technologies merely because one incorporated earlier, undertook research within a university before spinning out, or encountered a longer clinical or regulatory pathway.

Research Australia maintains that the preferred solution is to remove the age limit. If Treasury considers a temporal limit necessary, the legislation should provide an extension

⁴ Research Australia; Treasury Laws Amendment (Research and Development Tax Incentive) Bill 2019: Response to the Inquiry by the Senate Economics Legislation Committee (March 2020); p 7-8.

based on objective evidence of continued innovation and commercialisation activity rather than a narrow product category.

2. The therapeutic goods test must reflect how modern health technologies are developed

If the 15-year extended pathway is retained, it should reflect how health technologies are now developed, not only the final regulated product. It must clearly cover in vitro diagnostic devices, other diagnostics and medical devices, as well as medicines and treatments.

Drafting focused on "new knowledge about therapeutic goods or their therapeutic use" risks being read as directed primarily to medicines and treatments. Diagnostics frequently generate information about a patient or disease and are integral to clinical decision-making but may not directly concern the therapeutic use of a product.

Research Australia also recommends that the pathway extend to clinical manufacturing and to the adjacent and enabling activities on which therapeutic goods depend, including AI-enabled drug discovery, genomics, bioinformatics, advanced manufacturing and platform technologies. This work often precedes the point at which a product is identifiable as a therapeutic good, or serves several products at once, so a test tied to knowledge about a specific good may exclude it. The test should recognise R&D directed to developing therapeutic goods, including through enabling technologies and platforms.

Objective markers could include TGA or comparable overseas regulatory engagement; human research ethics approval; registration of a clinical trial; competitive MRFF, NHMRC or industry innovation funding; and patents. The legislation or instrument should allow more than one pathway so that eligibility does not depend on a single funding program or regulatory stage.

3. Supporting R&D activities should be retained

Removing eligibility for supporting R&D activities would fall disproportionately on health and medical innovators, even alongside the proposed increase to the core offset rate to 4.5%. As has already been acknowledged in this submission, developing a therapeutic good routinely takes more than a decade. It is a highly regulated process spanning discovery, preclinical research, clinical trials and clinical manufacturing, and it cannot progress without regulatory, manufacturing, quality assurance and analytical work. This work is inseparable from the core R&D activity. A clinical trial cannot lawfully begin or continue without it, and it includes activity such as GMP production of clinical-grade material, sourcing and qualifying inputs, regulatory strategy, data management, and the scientific oversight that keeps multi-site, multi-year programs traceable and defensible. Analysis for Australian life sciences companies undertaken by AusBiotech indicates that removing supporting activities from FY2029 would cut refundable offsets by up to 60% without any change to the underlying science, risk or regulatory requirements. Requiring each of these items to qualify as R&D in its own right would exclude work that is genuinely essential to the experiment.

Research Australia's preferred position is that supporting activities be retained in full. In answer to Treasury's question in the consultation, the cost of manufacturing for clinical trials should remain eligible. If the Government is not prepared to retain supporting activities generally, the legislation should, at a minimum, provide a defined list of eligible supporting activities developed in consultation with the sector, and should keep eligible any supporting work tied to a registered clinical trial or to regulatory requirements for a therapeutic good. A retained category of this kind would also give companies and their investors the certainty on eligibility that we address in section 5.

4. Genuine university and hospital spinouts must not be “born old”

Research organisations are often substantial shareholders in spinouts because they contribute intellectual property, facilities, expertise and early support. Rules that look through to connected entities or aggregate turnover can unintentionally attribute the age or revenue of a university, hospital or medical research institute to a newly formed company. A pre-revenue spinout could therefore fail the age or turnover test immediately, despite being the precise kind of business the incentive is intended to support.

The final legislation should provide that, for a genuine spinout, the relevant start date is the incorporation or commencement of business of the spinout itself. Institutional shareholdings should not, without more, aggregate the institution’s turnover with the spinout. Anti-avoidance rules aimed at recycled entities should be confined to arrangements whose dominant purpose is to restart the eligibility period and should not capture ordinary commercial restructures or the insertion of a holding company to facilitate investment.

Similarly, R&D conducted by a university before incorporation, or commissioned from a university after incorporation, should not prevent the company from qualifying. Guidance should explain how R&D registration dates, ownership of intellectual property and contracted research interact with the company-age and innovation tests.

5. Businesses and their investors need certainty when R&D expenditure is claimed

The incentive will influence investment decisions only if its availability can be assessed with confidence at the time expenditure is committed, not years after the fact. Under the current framework, a company self-assesses its R&D activities and expenditure at registration and at the time of lodging its tax return, but that self-assessment is not tested until a compliance review, which can occur up to four years after lodgement of the company’s tax return, and often after a refundable offset has already been paid out. This exposes companies, and the financiers, lenders and investors who rely on the expected offset as a cashflow input, to a prolonged period of retrospective uncertainty over eligibility determinations they cannot independently confirm at the time capital or resourcing decisions are made.

Research Australia recommends a low-cost binding determination or safe-harbour process, administered jointly by the ATO and Industry Innovation and Science Australia, that is materially more accessible than the current Advance Finding mechanism. Objective gateways should permit automatic qualification where specified evidence is held at the time of registration, while retaining a principles-based alternative for novel or cross-disciplinary R&D that does not fit a prescribed category. Determinations should be capable of being relied on by the claimant company and its financiers for the relevant income year, unless obtained through misrepresentation.

Case study: AlleSense

AlleSense is an Australian medtech company developing a new optical biosensor for the early diagnosis of cancer. Founded in 2023, it was spun out of La Trobe University and works in clinical partnership with a Melbourne-based medical research institute, translating fundamental nanophotonics research into an in vitro diagnostic (IVD) now undergoing clinical validation. AlleSense is an example of the kind of early-stage, research-intensive venture whose success would deliver wider benefits for health and the economy, and that the R&D Tax Incentive is designed to support.

“As a founder, the refundable R&D Tax Incentive is one of the few sources of funding that allows us to keep the science moving. The proposed changes risk pulling that support away from companies willing to bring fundamental Australian discovery science to patients.”

Distinguished Professor Brian Abbey
Co-founder and CTO, AlleSense

Like many medical technology companies, AlleSense is likely to carry tax losses while it funds development, even where some revenue is generated along the way, because commercialising a diagnostic requires clinical validation, regulatory approval and reimbursement. This makes the refundable R&D Tax Incentive one of the few sources of non-dilutive funding available to sustain its research during that period.

AlleSense reflects the long development pathway faced by university spinouts in medical technology. These companies can spend many years moving from university research through clinical validation and regulatory approval before they generate revenue. The proposed changes risk reducing R&D support during that period, when access to non-dilutive funding is often most important.

Implementation and review

Treasury should publish detailed guidance and worked examples before commencement, including examples for university spinouts, hospital partnerships, diagnostic companies, restructures and involuntary exits. The guidance should clearly state the evidence required at the time R&D activities are conducted and expenditure is incurred, and the records that companies and their financiers may rely upon.

The operation of the R&DTI should be reviewed in regular intervals to examine additionality, administrative burden, disputes, and whether it is continuing to effectively encourage investment in R&D, startups and other innovative businesses to reverse the decline in investment seen over more than a decade. It is critical to understand and adjust for unintended consequences of a reform such as this on different sectors.

Conclusion

Research Australia strongly believes the R&D Tax Incentive reforms should ultimately be assessed against the broader ambition articulated in *Ambitious Australia*: to reverse declining R&D investment, increase business investment in R&D, strengthen translation and commercialisation, and ensure Australian ideas generate economic, health and societal benefits. There is a risk that elements of the proposed reforms, such as those outlined in this submission could work against these objectives by reducing support at the critical point where research-intensive companies are translating discoveries, undertaking clinical and regulatory development, and moving towards commercialisation.

Research Australia recommends that the Government revise the exposure draft before legislation is introduced to the Parliament to ensure the R&D Tax Incentive strengthens, rather than constrains, investment and translation in health and medical

research and innovation. The Government should also assess the combined impact of these changes against the objectives of *Ambitious Australia*, including whether they will increase additional business R&D, support commercialisation and generate wider economic and societal spillovers. This alignment is essential if the R&DTI is to help translate Australia's research strengths into new products, companies, industries, jobs and improved health outcomes.

Thank you for the opportunity to provide a submission in response this consultation. Research Australia is committed to collaborating with governments, healthcare providers, researchers, industry partners, and communities to translate our recommendations into equitable outcomes that can be clearly measured and beneficial to all Australians.

For further information regarding this submission please contact Dr Talia Avrahamzon, Head of Policy, Projects and Advocacy at talia.avrahamzon@researchaustralia.org or policy@researchaustralia.org

Warm regards,



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