



Biointelect Venturer

Funding Guidelines

November 2025

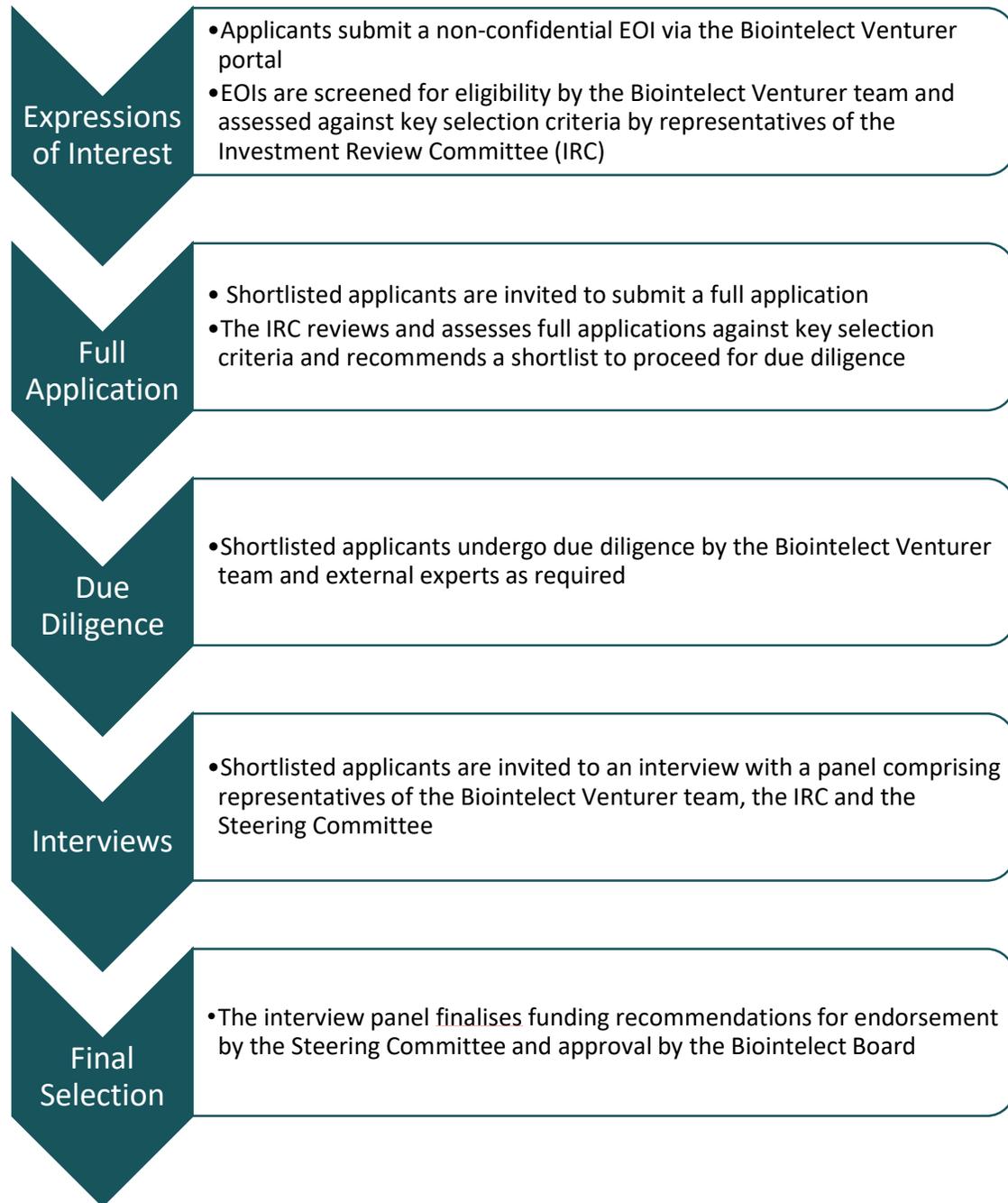
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Acronyms

AI – Artificial Intelligence
ABN – Australian Business Number
AUD – Australian Dollar
BMTI – BioMedTech Incubator
CAG – Consumer Advisory Group
CMC – Chemistry, Manufacturing and Controls
CRO – Contract Research Organisation
EOI – Expression of Interest
FTE – Full-Time Equivalent
GMP – Good Manufacturing Practice
IND – Investigational New Drug
IP – Intellectual Property
IRC – Investment Review Committee
MRFF – Medical Research Future Fund
NIH – National Institutes of Health
SME – Small-to-Medium Enterprise
TPP – Target Product Profile
TRL – Technology Readiness Level

Biointelect Venturer Application & Selection Process



Note: All recommendations made by the Investment Review Committee will be endorsed by the Steering Committee and approved by the Biointelect Board.

1 About Biointelect Venturer

1.1 About Biointelect Venturer

Biointelect Venturer is Australia’s first national virtual incubator established to accelerate the development of preventative health technologies – with a focus on vaccines, immunotherapies and related technologies targeting infectious diseases – from concept to investment readiness.

Biointelect Venturer is funded by the Australian Government’s Medical Research Future Fund (MRFF) 2024 BioMedTech Incubator Grant Opportunity via the Department of Health, Disability and Ageing.

Biointelect Venturer will support Australian small-to-medium enterprises (SMEs) through key phases of early-stage development, including pre-clinical, clinical and commercialisation activities. The program is designed to accelerate promising vaccine and infectious disease innovations, transforming early breakthroughs into investment-ready solutions and enabling access to follow-on funding.

www.biointelect.com/biointelect-venturer

1.2 About Biointelect

Biointelect is a globally recognised Australian company offering a unique blend of full-service Contract Research Organisation (CRO), regulatory and commercialisation capabilities. With deep roots across the health innovation ecosystem, Biointelect provides end-to-end support across the entire development pathway from early-stage research through to market access and health system integration.

www.biointelect.com

2 Biointelect Venturer Program

2.1 Program Overview

Biointelect Venturer provides targeted, milestone-based financial and non-financial support to bridge the gap between concept and investment readiness — including non-dilutive funding, expert guidance and training, market orientation, and access to a national and international network of partners.

Biointelect Venturer will provide AUD 25 million in non-dilutive funding over four years, distributed across three cohorts, following a competitive application and selection process. Funding and commercialisation support will be tailored to the Technology Readiness Level (TRL; Table 1) and needs of each project, with:

- Applicants at Technology Readiness Level (TRL) 3 to 4: eligible for up to AUD 1.5 million to support pre-clinical and clinical product development and commercialisation activities. Projects at TRL 2 may be considered in exceptional cases, if they are about to progress to TRL 3 or have a credible plan to achieve TRL 4 within two years.
- Applicants at TRL 5 to 6: eligible for up to AUD 3 million to support pre-clinical and clinical product development and commercialisation activities.

Table 1: Overview of Technology Readiness Levels (TRLs; adapted from the National Institutes of Health (NIH) Centers for Accelerated Innovations¹)

Technology Readiness Levels (TRL)							
1	2*	3	4	5	6	7	8
Review of Scientific Knowledge Base	Development of Product Hypothesis	Identification and Characterisation of Product Candidate	Optimisation and Initial Demonstration of Safety and Efficacy	Advanced Characterisation of Product and Initiation of Manufacturing	Regulated Production, Regulatory Submission, and Clinical Data (Phase I Clinical Trials)	Scale-up, Initiation of GMP Process Validation, and Phase II Clinical Trials	Completion of GMP Validation and Consistency Lot Manufacturing, Phase III Clinical Trials
Discovery Research and Idea Generation		Preclinical Testing and Feasibility			Early Clinical Studies and Product Development	Late Clinical Studies and Evidence Building	
Not eligible		Eligible				Not eligible	

*Projects at TRL 2 may be considered in exceptional cases if they are about to progress to TRL 3 or have a credible plan to achieve TRL 4 within 2 years.

Note: a comprehensive TRL framework, including details about activities and milestones extracted from the NIH Centers for Accelerated Innovations, is provided as Appendix 1.

Successful SMEs will have up to two years to complete project activities agreed as part of the application and selection process. Funding will be released in tranches aligned to commercially relevant milestones and the successful navigation of agreed Go/No-Go points.

Given that funding is milestone-based, some SMEs may not meet milestones early in their development program and therefore may not continue to receive funding. Applicants may apply for top-up funding of up to a maximum of AUD 5 million per project, subject to meeting agreed conditions.

Examples of activities Biointelect Venturer funding may support include:

- Product development strategy (including Target Product Profile development)
- Portfolio prioritisation and market assessments
- Product development and business planning
- Funding and investment strategy development
- Regulatory authority and safety studies supporting first-time-in-human studies ('IND-enabling') e.g. non-clinical toxicology; Chemistry Manufacturing Controls (CMC)
- Investigator's Brochure preparation

¹https://ncai.nhlbi.nih.gov/ncai/resources/docs/Technology_Readiness_Guidelines%20NCAI%2021June2018.xlsx

- Regulatory strategy and submissions
- Early-phase clinical studies

In addition to non-dilutive funding, successful applicants will receive hands-on commercialisation support to navigate the complex journey from early-stage development to commercial and investment readiness including:

- Guidance from dedicated Biointelect Venturer Project Consultants
- Access to matched mentors with relevant expertise
- A Target Product Profile (TPP) overview workshop
- Three masterclasses focused on key challenges and opportunities for commercialisation
- Access to infrastructure, specialist facilities and advisors
- Access to curated investor and funder networks

3 Eligibility Criteria

3.1 Eligibility Criteria

To be eligible for the Biointelect Venturer incubator, applicants must meet the following requirements:

Entity type:

- Be an Australian small-to-medium enterprise (SME) (i.e. a registered Australian corporate entity² with an ABN employing no more than 199 employees)
- Be a researcher at an Australian University or Medical Research Institute that will commit to incorporating a new company that meets the above SME requirements prior to award of funding. Biointelect Venturer funding will not cover the cost of company formation or incorporation. Any expenses related to establishing a new entity, such as legal, accounting or administrative fees, must be borne by the applicant or their host institution.

Not-for-profit enterprises are eligible to apply provided they meet the other eligibility criteria, including demonstrating a clear pathway to commercialisation.

Large companies with over 200 employees, unincorporated entities, sole traders, and companies registered outside Australia are not eligible.

Multiple applications

Each SME may submit only one application under this funding round. Universities, Medical Research Institutes, and other publicly funded research organisations may put forward more than one proposal, provided each relates to a distinct project. Where multiple submissions are coordinated by the same organisation, every project must be clearly differentiated and, where relevant, include its own ABN or ACN.

² <https://www.asic.gov.au/for-business-and-companies/business-basics/>

Australian Operations and local activity

Biointelect Venturer funding is intended to support local innovation from Australian SMEs that are registered in Australia and operate primarily within the Australian innovation ecosystem.

An Australian-incorporated subsidiary of an international company may be eligible, provided:

- It is a registered incorporated Australian entity with an ABN
- It employs fewer than 200 staff
- It conducts substantive project activities in Australia
- Intellectual Property (IP) ownership for the technology resides in Australia

However, subsidiaries that act primarily as sales, distribution, or administrative offices for overseas parent companies, or where decision-making and IP ownership reside offshore, are not eligible.

Intellectual property:

- Applicants must hold or secure transferable rights to required background IP, with access on commercial terms for market entry, and confirm no blocking IP will impede the project.
- Applicants applying prior to incorporation must demonstrate a credible plan to secure and transfer required IP to the new entity before execution of the funding agreement.

Biointelect Venturer does not seek or retain ownership of any IP arising from or associated with funded projects. All IP remains with the participating organisation or company.

Area of focus

- Projects developing innovations for the prevention of infectious diseases that address public health priorities with high unmet clinical need and/or clear global or regional health-security benefit and show strong commercialisation potential. This includes zoonotic and vector-borne diseases, or cancers caused by infectious agents.

To be eligible, a project's lead indication must directly address the prevention of a defined infectious disease, rather than the management or treatment of another condition that directly or indirectly affects infection risk.

Projects aimed at preventing or treating non-infectious diseases or that focus solely on the treatment or management of established disease, without a preventative component, are not eligible.

Modalities:

This incubator is focused on innovations that prevent or control infectious diseases through the following modalities:

- Prophylactic vaccines
- Prophylactic immunotherapies
- Related technologies (e.g. delivery systems, adjuvants or platforms) that enable or enhance the prevention of infectious diseases

Other modalities that reduce infection risk or transmission — and are generally considered part of prevention strategies — such as diagnostics, biomarkers and prophylactic drugs, will also be considered based on their impact on the infectious disease prevention landscape.

Therapeutic interventions intended primarily to treat existing infections or diseases, host-directed therapies that reduce symptoms after infection onset, as well as Artificial Intelligence (AI) and digital health tools, software as a medical device, or devices designed solely to treat or manage established infections, are not eligible.

Stage of development:

- Technologies must be at TRL 3-6 (as defined by the NIH Centers for Accelerated Innovations (2018) TRL framework; refer to Appendix 1) at the time of application.
- Projects at TRL 2 may be considered in exceptional cases if they are about to progress to TRL 3 or have a credible plan to achieve TRL 4 within two years. Projects greater than TRL 6 are out of scope.

Other requirements:

- Applicants must provide a letter of support from their Board/Executive leadership (for established companies) or Business Development Manager/Tech Transfer office (for researcher-led applicants at Australian-based Universities and Medical Research Institutes).
- Applicants must agree to reporting and monitoring requirements, including providing outcomes data and other metrics as requested during the program.

4 Application & Selection Process

4.1 Governance and Evaluation Committees

The Biointelect Venturer selection process includes expert review by the Biointelect Venturer **Investment Review Committee** (IRC). The IRC is an independent committee, composed of nationally and internationally recognised experts with deep expertise spanning vaccine and therapeutic product development, infectious diseases, pre-clinical and clinical development, regulatory affairs, and manufacturing and process development. Members also bring substantial experience in local and international funding, investment, market access, commercialisation and intellectual property management.

IRC recommendations are endorsed by the Biointelect Venturer **Steering Committee** and approved by the Biointelect Board prior to award and contracting.

The Steering Committee is an independent, nationally representative advisory group that provides expert advice on the establishment and operations of the incubator under the terms of the Commonwealth Agreement and MRFF award. It is responsible for reviewing and endorsing IRC recommendations for consideration and approval by the **Biointelect Board**.

The **Consumer Advisory Group (CAG)**, consisting of 6–8 consumers from diverse backgrounds, provides a complementary perspective within the incubator’s governance framework by ensuring that consumer and community views inform program design and decision-making.

All committee members are appointed under Biointelect’s Confidentiality and Conflict-of-Interest Policy. Any real or perceived conflicts are declared and managed to ensure a fair, transparent, and unbiased decision-making process.

4.2 Application & Selection Process

The Biointelect Venturer application and evaluation process ensures a rigorous and independent assessment through a structured multi-stage framework.

- **Expression of Interest:** Applicants submit a non-confidential Expression of Interest (EOI) via the Biointelect Venturer application portal. The EOI must summarise the opportunity, its relevance to infectious disease prevention, current stage of development, IP position, high-level development plan and budget, and proposed commercialisation pathway.

EOIs will be screened for eligibility by the Biointelect Venturer team and evaluated against key selection criteria by representatives of the IRC. Shortlisted EOIs will be endorsed by the Biointelect Venturer Steering Committee, approved by the Biointelect Board and invited to submit a full application. Feedback will be provided to shortlisted applicants to support preparation of the full application.

- **Full application:** Shortlisted applicants are invited to submit a full application that expands on the EOI and addresses any feedback received. Full applications should clearly articulate the commercialisation pathway, milestone-driven development plan and approach to risk management. The IRC will assess full applications against key selection criteria to select a shortlist for due diligence review.
- **Due diligence:** Shortlisted full applications will undergo due-diligence review by the Biointelect Venturer team to verify IP ownership, assess financials and business structure and identify potential risks before progressing to interview. These applications and associated due-diligence reports will be endorsed by the Biointelect Venturer Steering Committee.
- **Interviews:** Top-ranked applicants will be invited to an interview with a panel comprising representatives of the Biointelect Venturer team, the IRC and Steering Committee. Applicants will have the opportunity to present their project and respond to expert questions. The interview will focus on the applicants’ motivation, communication skills, ability to address identified risks, coachability, and readiness for incubation.
- **Final selection:** Funding recommendations are finalised by the interview panel and submitted for endorsement by the Steering Committee and approval by the Biointelect Board.

4.3 Selection Criteria

The following selection criteria (Table 2) are used to assess applications and identify projects demonstrating strong scientific merit, clinical relevance, and commercial potential.

Table 2: Selection criteria

Criteria	What Biointelect Venturer looks for in applications
Unmet need and potential impact	A clearly defined public health or clinical gap, supported by evidence of disease burden and end-user or patient need, and a clear articulation of how the proposed solution could deliver meaningful population-level and/or market impact
Scientific and technical merit	A robust scientific rationale supported by credible data that demonstrate feasibility, reproducibility, and potential for scale. The project should meet the relevant definition of Technology Readiness Level (TRL) (see Appendix) and present a credible pathway to advance to the next stage of development and/or TRL(s).
Project Plan and budget	A well-defined, milestone-driven development plan aligned with the broader translational pathway to market, including measurable deliverables, clear Go/No-Go decision points, realistic timelines, and an appropriate, justified budget aligned with project scope and stage of development.
Leverage and criticality of Biointelect Venturer funding	A clear explanation of how Biointelect Venturer funding will be leveraged (e.g. through co-funding, partnerships, or follow-on investment) and why this support is essential at the current stage to achieve the proposed outcomes. The application should clearly demonstrate what this funding uniquely enables that existing resources cannot.
Risk and feasibility	Identification of key competitive, technical, operational, regulatory, and commercial risks, with corresponding mitigation strategies and evidence of adaptive planning to manage uncertainties.
Competitive positioning	A clear differentiation between this project and competing or alternative solutions, demonstrating how the innovation advances beyond current or emerging approaches in performance, usability, accessibility, or cost.
Intellectual property	Evidence of secure or negotiable IP rights for the core technology, with a strategy to establish or maintain freedom to operate and protect commercial value.
Team capability and resources	A committed, multidisciplinary and diverse team with demonstrated expertise, appropriate resources, and access to required infrastructure or partners to deliver the proposed milestones.
Consumer or end-user consideration	Demonstrated relevance and responsiveness to end-user needs, supported by evidence of planned or existing engagement activities.
Pathway to translation and commercialisation	A credible route to market or partnership, including plans for follow-on funding, collaboration, or investment that support long-term sustainability and Australia's sovereign capability in infectious disease prevention.

4.4 Key Dates

Table 3: Key application dates for Cohort 1

2025 Funding Round	Dates
EOIs open	17 November 2025 at 9:00 am (AEDT)
EOIs close	19 December 2025 at 11.59 pm (AEDT)
EOI outcome notifications	Mid-February 2026
Full applications open	
Full applications due	Mid-April 2026
Interviews	Early July 2026
Full application outcome notifications	From Q3 2026
Funding agreements executed and project commencement	From Q3 2026

Note: Key dates for the full application and interviews will be communicated to shortlisted applicants.

4.5 Applicant Support

To help applicants prepare high-quality, commercially focused submissions, Biointelect Venturer will host information sessions during the EOI period.

Program information sessions

Two online information sessions will be hosted to introduce the program, outline eligibility and assessment criteria, and walk applicants through the application process. These sessions will also include practical tips for developing a competitive proposal.

2025 session details

Session 1

- **Date:** Thursday, 20 November 2025
- **Time:** 12:00 pm AEDT

Session 2

- **Date:** Tuesday, 25 November 2025
- **Time:** 1:00 pm AEDT

Following each live session, a recording and slide deck will be made available on the Biointelect Venturer webpage: www.biointelect.com/biointelect-venturer

Applicants are encouraged to attend one of the webinars or view the recording before finalising their submission.



Applicant Enquiries

The Biointelect Venturer mailbox is monitored during business hours to ensure that applicant enquiries are addressed promptly. The Biointelect Venturer team will aim to respond to all enquiries within three (3) business days.

To ensure equal access to information, Biointelect Venturer may publish de-identified questions and responses from potential applicants on the program's **Frequently Asked Questions (FAQs)** page. If your enquiry contains confidential information, please clearly indicate this in your correspondence, so it is not shared publicly.

Biointelect Venturer accepts no responsibility for the disclosure of information submitted outside the formal application process unless it has been expressly marked as confidential. In all cases, Biointelect Venturer will not disclose the identity of the organisation or individual submitting a question.

5 FAQs

Q: Can I talk to someone about the program or my application?

Yes. Once you have reviewed the program guidelines and confirmed your eligibility, you may contact the Biointelect Venturer team to discuss your application.

To ensure a fair and transparent assessment process, applicants must not contact members of the Biointelect Venturer IRC, Steering Committee or Biointelect Board directly regarding their application or the selection process. Any enquiries received outside official channels will be referred to the Biointelect Venturer mailbox or enquiry booking form.

Q: Who assesses my application?

All eligible EOIs and full applications are assessed by the IRC — an independent committee of experts with experience spanning the scientific, clinical, and commercial translation of health technologies. All reviewers are bound by confidentiality and conflict-of-interest agreements.

Q: My project is currently at TRL 2. Can I still apply?

Projects should be between TRL 3 and 6 at the time of application. However, projects at TRL 2 may be considered by exception if they can demonstrate they are about to progress to TRL 3 or have a credible and achievable plan to reach TRL 4 within two years. Applicants seeking consideration under this exception should clearly justify their development pathway, provide supporting data that indicates imminent advancement, and outline key milestones to reach TRL 4. Exceptional consideration is at the discretion of the Biointelect Venturer IRC and Steering Committee.

Q: What types of therapeutic or disease-related projects fall within the scope of Biointelect Venturer?

Biointelect Venturer is focused on innovations that prevent or control infectious diseases in humans. This includes prophylactic vaccines, prophylactic immunotherapies, and related technologies (e.g. delivery systems, adjuvants, and molecular platforms) that reduce infection risk or transmission.

Other modalities that reduce infection risk or transmission — and are generally considered part of prevention strategies — such as diagnostics, biomarkers and prophylactic drugs, will also be considered based on their impact on the infectious disease prevention landscape.

The lead indication must directly address the prevention of a defined infectious disease, rather than the management or treatment of another condition that directly or indirectly affects infection risk.

Projects targeting non-infectious diseases, or those focused solely on treatment or management of established disease (without a preventative component), are not eligible. Likewise, therapeutic interventions intended primarily to treat existing infections, host-directed therapies that reduce symptoms after infection onset, and digital-health or AI-only tools without a direct preventative mechanism, are out of scope.

Q: Will Biointelect Venturer fund therapeutic vaccines or immunotherapies?

Biointelect Venturer is focused on innovations that prevent or control infectious diseases through prophylactic (preventative) vaccines and immunotherapies designed to prevent infection or control disease onset. Prophylactic immunotherapies include monoclonal antibodies for the prevention of disease.

Projects developing therapeutic vaccines or immunotherapies intended to treat existing infections or established disease as well as host-directed therapies that reduce symptoms after infection onset, are not within scope.

Q: Can an Australian subsidiary of an international company apply?

Biointelect Venturer funding is intended to support local innovation from Australian SMEs that are registered in Australia and operate primarily within the Australian innovation ecosystem. An Australian-incorporated subsidiary of an international company may be eligible, provided:

- It is a registered incorporated Australian entity with an ABN
- It employs fewer than 200 staff
- It conducts substantive project activities in Australia
- IP ownership for the technology resides in Australia

However, subsidiaries that act primarily as sales, distribution, or administrative offices for overseas parent companies, or where decision-making and IP ownership reside offshore, are not eligible. Applicants must clearly outline the entity structure, ownership, and IP arrangements within their submission to confirm compliance with program requirements.

Q: Can an Australian SME apply in partnership with an international company?

Yes. Collaborations between an eligible Australian SME and international partners are eligible where they strengthen the proposed project - for example, by providing access to specialised expertise, technology, or facilities not available in Australia.

However:

- The lead applicant must be the Australian SME, which must meet all eligibility criteria (including being a registered Australian entity with an ABN and employing fewer than 200 staff).
- The majority of project activities and expenditure must occur in Australia (in line with MRFF requirements).
- Any overseas components must be clearly justified as essential to achieving project objectives and approved in advance.

International partners may participate under subcontract or collaboration agreements, but they cannot receive direct funding from Biointelect Venturer.

Q: What happens to the information I submit?

All information provided through the Biointelect Venturer application portal is handled in accordance with Biointelect's privacy and data-management policies (www.biointelect.com/privacy). Application materials are treated as commercial-in-confidence. All IRC members, reviewers, and Biointelect staff involved in the assessment process are required

to sign confidentiality and conflict-of-interest declarations before accessing application information.

Q: Does Biointelect Venturer fund clinical trials?

Biointelect Venturer funding supports technologies between TRL 3 – 6 and will therefore support early-stage clinical or translational studies that are critical to demonstrating feasibility, safety or preliminary efficacy. Projects beyond TRL 6 – including those proposing large-scale pivotal trials - are considered out of scope. Please refer to Appendix 2 in the Funding Guidelines for eligible expenditure categories.

Q: How will funds be released?

Funding will be released in tranches aligned with agreed milestones as outlined in the approved project plan. Continued funding is subject to satisfactory progress against agreed deliverables and reporting obligations.

Q: Do applicants need to provide matched funding?

No. Matched funding is not required, but projects demonstrating co-funding, in-kind contributions, or partnerships that amplify Biointelect Venturer’s investment will be viewed favourably.

Q: Can Biointelect Venturer funding be combined with other funding or held alongside MRFF or other government grants?

Yes. Applicants may combine Biointelect Venturer funding with other non-Commonwealth sources, such as industry partnerships, venture capital, or philanthropic investment. Projects demonstrating co-funding, in-kind contributions, or partnerships that amplify Biointelect Venturer’s investment will be viewed favourably.

Applicants who already hold MRFF, NHMRC, or other government funding may also apply, provided the proposed Biointelect Venturer activities are distinct, non-overlapping, and complementary to any existing government-funded work. Biointelect Venturer cannot support specific activities, equipment or supplies already funded through another MRFF, NHMRC, or government grant.

All existing or planned funding arrangements must be disclosed in the application and confirmed prior to contracting.

Q: What is the IP policy for Biointelect Venturer?

IP arising from projects remains the property of the participating organisation or company. Biointelect does not claim ownership or rights to participant IP. However, applicants must hold or secure rights to the core IP necessary to deliver the project and must outline how future IP will be protected, managed, and commercialised.

Q: Can researchers from Universities or Medical Research Institutes apply?

Yes. Researchers based at Australian Universities, Medical Research Institutes or hospitals are eligible to apply if they commit to establishing a new company that meets the SME eligibility requirements prior to contracting. Biointelect Venturer funding cannot be used to cover incorporation or company formation costs. Applicants must ensure their institution supports company creation within the proposed timeframe.

Applicants should ensure that proposed project activities are operationally distinct from institutional research and that IP ownership and contracting arrangements are clearly defined and transferable to the new entity.

Q: Can Biointelect Venturer funding be used for IP-related costs?

Funding may support IP-related strategic activities (e.g. freedom-to-operate analysis, IP strategy development, patentability assessments) if these are included in the approved project plan. Direct patent filing or maintenance fees are considered ineligible expenditure under MRFF funding guidelines.

Q: Can projects be modified after submission if selected?

Yes. Projects progressing to due diligence or contracting stages may be refined in consultation with the Biointelect Venturer team and the Investment Review Committee to ensure alignment with program objectives and maximum impact. Any changes will require formal approval before contracting.

Q: How does Biointelect Venturer manage probity and conflicts of interest?

All members of the Biointelect Venturer Investment Review Committee, Steering Committee, and advisory groups operate under strict confidentiality and conflict-of-interest policies. Any potential conflicts are declared and managed in line with best-practice governance standards to ensure fair, unbiased assessment.

Q: What happens if project milestones or reporting obligations are not met?

Biointelect Venturer funding agreements include milestone-based tranches. Continued funding is contingent on satisfactory progress and compliance. Biointelect Venturer reserves the right to withhold or terminate funding if obligations are not met or if material non-compliance occurs.

Q: Will information about my project be made public?

All application information is treated as commercial-in-confidence during the review process. However, Biointelect Venturer may publicly announce successful applicants and use non-confidential project summaries for communication, reporting or promotional reporting purposes. Non-confidential summaries will be provided to successful applicants for approval prior to publication. Confidential information will not be disclosed without consent.

Q: Will applicants receive feedback on their submissions?

Applicants not progressing beyond the EOI stage will not receive individual feedback, due to the expected high volume of submissions. Shortlisted applicants invited to submit a full application will receive summary feedback to guide the next stage of submission.



6 Contact Information

For more information about Biointelect Venturer visit: www.biointelect.com/biointelect-venturer

For any enquiries, please contact venturer@biointelect.com

7 Appendices

Appendix 1: Technology Readiness Level Framework

To help applicants determine the current development stage of their technology, the following framework outlines the detailed descriptions of each TRL stage and typical activities associated with them, as described by the NIH Centers for Accelerated Innovations (2018).

Table 4: Technology Readiness Levels (TRLs) for a Drug or Biological

TRL 1	TRL 2	TRL 3	TRL 4	TRL 5	TRL 6	TRL 7	TRL 8
Basic Description							
Review of Scientific Knowledge Base	Development of Product Hypothesis	Identification and Characterisation of Product Candidate	Optimisation and Initial Demonstration of Safety and Efficacy	Advanced Characterisation of Product and Initiation of Manufacturing	Regulated Production, Regulatory Submission, and Clinical Data	Scale-up, Initiation of GMP Process Validation, and Phase 2 Clinical Trial(s)	Completion of GMP Validation and Consistency Lot Manufacturing, Clinical Trials Ph3, and FDA Approval or Licensure
Activities							
Scientific findings are reviewed and assessed as a foundation for characterising new technologies	<p>Scientific studies to identify and validate disease target.</p> <p>Screen potential compounds (HTS, antibody, etc) to develop preliminary hits.</p> <p>Develop assays to test activities of candidate compounds in vitro.</p> <p>Initial intellectual property (IP) search for patentability.</p> <p>Characterise disease epidemiology.</p>	<p>Decision on which compounds to advance in development.</p> <p>Synthesise novel series of compounds, test efficacy and toxicities in vitro.</p> <p>Test PK/tox of selected compounds in relevant in vivo models on a non-GLP level.</p> <p>Survey relevant patent literature to identify white space and assess patentability of compound series.</p> <p>Survey clinical literature to characterise current care patterns and unmet need(s).</p> <p>File a provisional patent on the pharmacophore.</p>	<p>Initiate experiments to identify markers, assays, and endpoints for further non-clinical and clinical studies.</p> <p>Assess endpoints for relevant impact in clinical practice.</p> <p>Conduct in vivo distribution and elimination studies</p> <p>Non-GLP in vivo toxicity and efficacy of lead compound; pharmacokinetic studies.</p>	<p>Develop a scalable and reproducible manufacturing process amenable to GMP.</p> <p>Develop assays/analytical methods for product characterisation and release (potency, purity, ID, sterility, etc).</p> <p>Perform IND-enabling toxicology studies.</p> <p>Identify KOLs that can help design a clinical trial strategy/sequence, including collection of health economic and longer-term patient outcomes measures.</p> <p>Identify clinical sites and begin contract negotiations.</p> <p>Begin stability testing on drug substance (i.e., API).</p>	<p>Prepare and submit IND. Initiate Phase I study.</p>	<p>Post Phase 2 meeting with FDA.</p> <p>Determine dosing and treatment population for Phase 3 study.</p>	

		Synthesise and assess several potential lead compounds.					
Milestones							
	Identify compound series	<p>Demonstrate in vitro efficacy.</p> <p>Preliminary efficacy demonstrated in vivo in appropriate small animal model.</p> <p>Identify lead series. File patent.</p>	<p>Finalise formulation appropriate for route of administration.</p> <p>Draft Product Profile. Determine Regulatory strategy.</p> <p>Characterise current reimbursement mechanisms, economic burden of illness and treatment costs. Identified preclinical candidate compound and animal models for GLP tox studies.</p>	<p>Identify candidate.</p> <p>Demonstrate acceptable ADME characteristics and/or immune responses in GLP animal studies as necessary for regulatory filing.</p> <p>Identify manufacturing partners.</p> <p>Pre-IND meeting with FDA. First draft of a target product profile/package insert.</p>	<p>Manufacture GMP-compliant pilot lots.</p> <p>Prepare and submit regulatory package to FDA and conduct Phase 0 and/or 1 clinical trial(s) to determine the safety and pharmacokinetics of the clinical test article.</p>	<p>Scale-up and validate GMP manufacturing process at a scale compatible with USG requirements.</p> <p>Complete stability studies of the GMP drug product in a formulation, dosage form, and container consistent with Target Product Profile.</p> <p>Complete Phase 2 clinical trials.</p>	<p>Finalise GMP manufacturing process.</p> <p>Complete clinical efficacy trials (e.g., Phase 3), and/or expanded clinical safety trials as appropriate.</p> <p>Prepare and submit New Drug Application or Biologics Licensing Application NDA/BLA.</p>

Table 5: Technology Readiness Levels (TRLs) for a Diagnostic

TRL 1	TRL 2	TRL 3	TRL 4	TRL 5	TRL 6	TRL 7	TRL 8
Basic Description							
Review of Scientific Knowledge Base	Development of Product Hypothesis	Identification and Characterisation of Product Candidate	Optimisation and Initial Demonstration of Safety and Efficacy	Advanced Characterisation of Product and Initiation of Manufacturing	Regulated Production, Regulatory Submission, and Clinical Data	Scale-up, Initiation of GMP Process Validation, and Phase 2 Clinical Trial(s)	Completion of GMP Validation and Consistency Lot Manufacturing, Clinical Trials Ph3, and FDA Approval or Licensure
Activities							
Active monitoring of scientific knowledge base. Identify links between disease in humans and animals.	Scientific "paper studies" to generate research ideas, hypotheses, and experimental designs for addressing the related scientific issues. Characterise disease epidemiology. Initial intellectual property search for patentability.	Explore assay components via prototypes and screening; identify and evaluate critical technologies and components and begin characterisation of lead design. Survey clinical literature to characterise current care patterns and unmet need(s). Initiate user feedback	Integration of critical technologies and components (including hardware and software). Select appropriate candidate reference and QC (quality control) reagents.	Activities: Design freeze. Develop a scalable and reproducible manufacturing process aligned with regulatory guidelines (as needed). Finalise QC criteria.			N/A
Milestones							
		Demonstrate preliminary assay with simplified sample/artificial matrices. Demonstrate sensitivity and specificity with spike/recovery studies in the appropriate matrices.	Assay/ test method validation in accordance with the product's intended use (Sample type, volume, assay components). Establish Draft TPP. Outline current reimbursement mechanisms, economic burden of illness and treatment costs. Formulate initial regulatory and reimbursement strategies.	Identify supply chain and/or manufacturing partners. Demonstrate acceptable performance as necessary for regulatory filing and for impact on clinical care—preliminary FDA meeting.	Manufacture product compliant with quality protocols. Based on regulatory classification (e.g. CLIA vs IVD route), submit regulatory package	Assays used to assess product quality are validated. Assays used to assess critical outcomes in clinical trials and in animal efficacy studies are validated.	

Appendix 2: Biointelect Venturer eligible use of funds

All funding provided through Biointelect Venturer must comply with the 2024 Medical Research Future Fund (MRFF) BioMedTech Incubator (BMTI) Grant Opportunity Guidelines on eligible expenditure.

Funding will only be used for approved project activities as defined in the executed funding agreement between the SME and Biointelect. If your application is successful, you may be required to provide evidence, such as quotes for major project costs.

Not all expenditure on your project may be eligible for grant funding. All costs must be incurred within the agreed project period unless otherwise specified.

Eligible and ineligible expenditure is outlined below (adapted directly from the MRFF BMTI Grant Opportunity Guidelines). For clarification on whether specific costs meet eligibility requirements, applicants are encouraged to contact the Biointelect Venturer team prior to submission.

Eligible Expenditure

Equipment

- Funding may be used to purchase equipment that is essential to achieving project objectives and outcomes.
- Applicants must justify why each item is critical to the proposed research and why it cannot be accessed through existing institutional resources.
- Applicants can request funding for equipment costing over AUD 10,000 that is essential to the research. The total equipment cost requested must not exceed 5% of the total grant amount up to a maximum of AUD 80,000.
- Applicants must be prepared to cover all service, maintenance, and repair costs for funded equipment.
- Computers are not eligible unless they are integral to specialised laboratory equipment or essential for processing large scientific datasets.
- Requests must include:
 - the purpose and use of each item,
 - its estimated cost, and
 - an explanation of why institutional equipment cannot be used.

Labour expenditure

- Direct labour costs of employees working on the core project activities. Labour costs must relate to personnel directly employed by the applicant and paid a regular salary or wage with standard tax deductions.
- Eligible roles may include technical, scientific, administrative, and project management staff, where there is a clear and measurable link to project objectives.
- Labour costs for leadership or administrative roles (e.g. CEO, CFO) are eligible up to 10% of total labour expenditure.
- Eligible salary expenditure includes labour on-costs including the employee's total remuneration package, including employer-paid superannuation, payroll tax, workers compensation, and standard leave entitlements.
- The maximum claimable salary for any individual (including packaged components) is AUD 175,000 per annum. Salary claims must be pro-rated for project periods shorter than one

year. Salary costs can only be claimed for time directly spent on project activities during the approved project period. There needs to be an auditable record of time spent on the project.

- Commonwealth-funded positions can be considered eligible to count towards an in-kind contribution. However, the Commonwealth-funded position cannot also draw a salary from funds awarded through this grant opportunity for the same activity.
- You may include eligible salary costs (on-costs) such as employer paid superannuation, payroll tax, workers compensation insurance, and leave entitlements (including paid maternity leave, sick leave, long service leave and recreation leave). These costs must be reasonable and be separately identified in the project budget. On-costs are considered separate and are not included as part of the salary cap.
- You should calculate eligible salary costs using the formula below:

$$\text{Eligible salary costs} = \frac{\text{Annual salary package} \times \text{Weeks spent on project}}{52 \text{ weeks}} \times \text{percentage of time spent on project}$$

- Evidence may include:
 - staff details (name, title, function, FTE commitment), and
 - employment contracts, pay slips, and ATO payment summaries.

Contract expenditure

- Contract expenditure covers costs of agreed project activities undertaken by external contractors or service providers.
- All contractors must have a written agreement in place before work commences (e.g., contract, letter of engagement, or purchase order).
- Contracts must specify the nature of work, deliverables, fees or hourly rates, and any associated costs.
- Invoices must include:
 - a detailed description of work completed,
 - time spent or quantities delivered, and
 - relevant expenses or materials charged.
- Contracted work must be directly linked to approved project activities and represent reasonable market value.
- Applicants must retain records of contractor costs and payments, including:
 - contracts or letters of agreement,
 - purchase orders or supply agreements, and
 - invoices and payment confirmations.
- Biointelect Venturer may request these records at any time; if adequate evidence cannot be provided, the expense may be deemed ineligible.

Overseas expenditure

- The majority of project activities and expenditure are expected to take place within Australia. Applicants may seek funding for specific project components to be conducted overseas only when the necessary equipment, expertise, or resources are unavailable in

Australia, and the activity is essential to achieving the project's objectives. Any overseas expenditure must first be approved by Biointelect Venturer for it to be considered an eligible expense.

Other Eligible Expenditure

Costs directly related to the project activity that are not already being supported through any other sources, or where other Commonwealth, state or territory governments do not have primary responsibility, including:

- Financial auditing of project expenditure,
- Costs you incur in order to obtain ethics and regulatory approvals during the project period. However, associated fees paid to the Commonwealth, state, territory and local governments are not eligible,
- Insurances which are specifically required to cover the grant activity, and/or
- Accessing expertise that supports the protection of IP.

Ineligible Expenditure

This section provides guidance on what is considered ineligible expenditure. Examples of ineligible expenditure include:

- Patent filing
- Maintenance or upgrades on buildings or structures,
- Activities, equipment or supplies that are already being supported through other sources or where other Commonwealth, state or territory governments have primary responsibility,
- Reimbursement of activities that have commenced prior to the execution of a grant agreement,
- Costs incurred prior to the project (Activity) start date,
- Retrospective costs,
- Any in-kind contributions
- Financing costs, including interest,
- Debt financing,
- Costs related to obtaining resources used on the project, including interest on loans, job advertising and recruiting, and contract negotiations,
- Non-project related staff training and development costs,
- Costs related to preparing the grant application, preparing any project reports (except costs of independent audit reports we require) and preparing any project variation requests,
- Conference attendance, and associated travel (except in pre-approved circumstances where the research outputs of the activity are to be presented),
- Health insurance, travel insurance, foreign currency, airport and related travel taxes, passports and visas,
- Entertainment and hospitality costs,
- Personal subscriptions (e.g., personal journal subscriptions),
- Personal membership of professional organisations and groups,
- Airline club membership,



- Communications costs (mobiles, telephone calls)
- Institutional overheads and administrative costs.

This list is not exhaustive and applies only to the expenditure of the grant funds. Other costs may be ineligible where we decide that they do not directly support the achievement of the planned outcomes for the project or that they are contrary to the objective of the grant opportunity.

Applicants must ensure they have adequate funds to meet the costs of any ineligible expenditure associated with the project.