

BIO INNOVATION SA Business Development Initiative

Guidelines for Applicants

The *Guidelines for Applicants* is a reference guide to be used when applying for a Bio Innovation SA Business Development Initiative Grant.

Further information on the Initiative is available directly from Bio Innovation SA or via the website: <http://www.bioinnovationsa.com.au>.

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1 Introduction

1.1 The Bio Innovation SA Business Development Initiative

Bio Innovation SA is a South Australian Government funded organisation established to enhance the development of the local bioscience industry.

Bio Innovation SA has established the Business Development Initiative (BDI) to assist South Australian bioscience companies to develop their business. BDI grants of up to \$250,000 can be used for a range of activities as described below in Section 1.2.

The BDI is open to start-up and early stage South Australian bioscience companies. Applications can be submitted year-round and will be reviewed internally by Bio Innovation SA. Applications will be assessed according to Merit Criteria (Section 3), which include the feasibility and commercial viability of the activities and the commercial expertise and skill of the management team.

The maximum amount of funding any one company can receive from all sources of grant funding Bio Innovation SA provides is \$250,000. Bio Innovation SA reserves the right not to award funding to any applicants under the BDI.

Please note that companies can apply for funds from Bio Innovation SA to support their participation in ARC Linkage grants through the BDI. Companies can also apply for funds to purchase major equipment through the Commercial Infrastructure (CI) Grant Scheme. The guidelines for the CI grant are available on the Bio Innovation SA website – www.bioinnovationsa.com.au.

1.2 Initiative Objectives

This Initiative aims to increase the success of commercialisation undertaken by bioscience (in particular biotechnology) companies in South Australia. The terms bioscience and biotechnology are defined in section 5.1. The BDI is positioned to provide early stage companies with funds to achieve key milestones to help develop their businesses and to raise equity finance.

Examples of eligible expenditure under the BDI are the costs of:

- a) incorporation and start-up costs for a new company;
- b) crucial “proof of commercial concept” experiments;
- c) the generation of supporting data to strengthen patent applications;
- d) specific professional advice (legal, patent, market, financial, accounting) for an identified project;
- e) training or travel of key individual(s); and
- f) projects that will achieve key milestones within a maximum of a 1-year timeframe.

It is anticipated that companies awarded BDI grants will receive ongoing advice and in-kind support from Bio Innovation SA.

Please note that BDI grants cannot be used to pay staff salaries and major equipment items. See the Bio Innovation SA website (www.bioinnovationsa.com.au) for other programs that may be applicable to cover salaries and major equipment items.

1.3 Level of Grant Support

The maximum size of a BDI grant is \$250,000 + GST.

Provided the applicant has not received funding previously from Bio Innovation SA, the requirement for matching of the grant funds by the applicant is dependent on the amount requested as follows:

- 1) Up to and including \$50,000 there is no requirement for matching funding;
- 2) Greater than \$50,000 and up to and including \$150,000 the applicant must provide matching funding of \$1 for every \$4 provided above \$50,000; and
- 3) Greater than \$150,000 and up to a maximum of \$250,000 the applicant must provide matching funding of \$1 for every \$2 provided above \$150,000.

Table 1: Examples of proposed amendments

Funding Requested	Matching Funding Required
\$50,000	\$0
\$150,000	\$25,000
\$250,000	\$75,000

NB. If the applicant has previously received funding from Bio Innovation SA, then please contact us to determine the level of matching funding required.

In the event that the funding pool is exhausted, applicants may need to delay application submission until the following financial year. Applicants should note that time restrictions may apply to the funding such that it must be expended within a specified time or be forfeited.

Bio Innovation SA will make payments for eligible activities either in arrears or upfront. To access funds awarded for the grant, a company must provide Bio Innovation SA with a tax invoice.

For grants paid in arrears, evidence of payment for the eligible activities must be included with the tax invoice. For grants paid upfront, evidence of payment for the eligible activities must accompany the final report. Evidence of payment should include a copy of a tax invoice from the supplier for the cost, and evidence that the invoice has been paid.

1.4 These Guidelines

These Guidelines have been prepared to assist applicants with their BDI grant application and provide information on eligibility requirements. Potential applicants will be provided with an Application Form when they are invited to apply for the grant, as described in Section 4.

2 Eligibility Requirements

The following requirements must be met for a company to be eligible for assistance:

- a) the applicant must be a South Australian bioscience company or individual(s)/organisation(s) in the process of forming a South Australian

bioscience company. In the case of the latter, a condition of the grant will be that the applicant registers a new South Australian company with the Australian Securities and Investment Commission (ASIC);

- b) the requested funding must be for activities that will achieve important commercial outcomes for the company;
- c) demonstrated access to existing and potential IP;
- d) the applicant must demonstrate that they are unable to fund the activities without financial assistance; and
- e) the applicant must be registered for the R & D Tax Concession.

The requirements to address each of these criteria are explained in Section 4, which covers the *Application Process* in detail.

3 Merit Criteria

Applications for grants will be assessed by Bio Innovation SA according to the following merit selection criteria:

- a) the feasibility and commercial potential of the company based on its IP position;
- b) the commercial experience and skill of the company's management team;
- c) the need for financial assistance;
- d) the extent to which the eligible activities will contribute to the development of the applicant's company; and
- e) the extent to which the eligible activities will provide benefits to South Australia.

The requirements to address each of these criteria are explained more fully in the Section 4.

4 The Application Process

The Bio Innovation SA BDI grant *Application Process* consists of three stages:

- a) potential applicants will submit a written (1-2 page) expression of interest to Bio Innovation SA for review;
- b) selected potential applicants will be invited to meet with Bio Innovation SA to discuss the proposal; and
- c) upon receipt of an invitation to apply, applicants will submit a full Application Form, provided by Bio Innovation SA.

At any of these stages, Bio Innovation SA may inform the potential applicant of its decision to decline to proceed with the application process.

4.1 Stage 1 – Submitting an Expression of Interest

This should be a succinct 1-2 page outline (a proforma can be obtained from Bio Innovation SA at http://www.bioinnovationsa.com.au/financial_support.htm) of the proposed project including the budget, timeframe, milestones and some background information on the technology and company. It should cover the key elements of the proposal in light of the stated objectives of the BDI. On the basis of the proposal, selected potential applicants will be invited to meet with Bio

Innovation SA to discuss the possibility of submitting an application. Bio Innovation SA will select potential applicants on the basis of how well the proposed project addresses the Merit Criteria, and whether the proposal outcomes lead to enhanced opportunities for business development.

4.2 Stage 2 – Meeting with Bio Innovation SA

Before submitting a full application for a BDI grant, it is important that potential applicants meet with Bio Innovation SA to discuss the activities that they would like funded. Potential applicants are welcome (and encouraged) to provide background information before the meeting and will need to be prepared to deliver a short (15-20 minute) and informal presentation on the company/proposed activities at the meeting. The meeting should be attended by the applicant company's business manager and an appropriate spokesperson(s) for the relevant technology.

The meeting provides the opportunity for potential applicants to receive feedback on their proposal and to be given informal advice on whether the activities are likely to be funded or what milestones will need to be achieved before an application will be considered. The meeting should be a constructive prelude to preparing the Application Form. It is common for more than one meeting to be held before a formal application is invited to be submitted.

4.3 Stage 3 – Application Form

The Application Form has been designed to allow applicants to address the Merit Criteria (Section 3) for this grant. It is anticipated that the space provided for each section will be sufficient to address each point and applicants are encouraged to be succinct.

5 Completing the Application Form

5.1 Part 1 – Applicant Details

A. Name of Applicant

The applicant must be a South Australian bioscience company or an individual(s)/organisation(s) planning to start a South Australian bioscience company. Preference will be given to those proposals with a strong biotechnology focus. The company must be located in South Australia for the duration of the project.

B. Fields of Bioscience and Biotechnology

For the purposes of this grant, the definition of biotechnology is *'The application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services'*.

Acceptable areas of biotechnology generally include, but will not be confined to:

- Human and Animal Therapeutics
- Plant Sciences
- Recombinant DNA Technology (Gene Technology)
- Bioinformatics
- Genomics

- Cell and Tissue Culture
- Applied Microbiology and Biochemistry
- Antibody and Protein Engineering
- Bioprocess Engineering
- Early Development Of Pharmaceutical And Veterinary Drug Manufacture
- Biological Materials, Biomembranes and Surfaces
- Environmental Biotechnology Developments

The field of bioscience includes the field of biotechnology and also includes the applications of diagnostics and medical and veterinary devices and the fields of pharmacy and nanotechnology, which act biologically or on biological agents.

Consistent with the Therapeutic Goods Administration, Bio Innovation SA defines a medical device as any technology, including device, software or diagnostic, intended to be used by human beings for the prevention, monitoring or treatment of a disease, injury or physiological process. A medical device must require regulatory approval from the Therapeutic Goods Administration or other similar overseas regulatory body in order to meet the definition.

Certain services provided to the bioscience industry may also be considered eligible. The Chief Executive of Bio Innovation SA will determine whether any proposed project falls within this definition for eligibility requirements.

C. & D. Appropriate Regulatory Approval

If the application includes a proof-of-concept study that will require appropriate regulatory approval (see below), the applicant will be asked to provide evidence of Ethics Committee or other regulatory approval or if approval has not yet been obtained, provide an anticipated date of approval being obtained.

When conducting research using genetic material from humans (including human embryos, stem cells and all other human organs, tissues and cells), animals or plants, and/or undertaking projects involving experimentation in humans (including human embryos, stem cells and all other human organs, tissues and cells) or animals, the applicant will be required to confirm that those activities:

- i) will have received formal prior approval by a qualified regulatory body(s) or committee(s) as complying with all relevant ethics codes and guidelines adopted by the National Health and Medical Research Council, the Office of the Gene Technology Regulator and all other relevant regulatory agencies operating in Australia and any other place in which the research will be conducted, that are applicable during the term of the project; and
- ii) will comply with all relevant legal requirements of the Commonwealth and any State or Territory of Australia, and of any other place in which the research will be conducted, that are applicable during the term of the project.

Applicants should note that copies of current ethical and regulatory approvals may be requested at any stage during the assessment process and, should a grant be given, during the term of the grant.

E. Nominated Contact Person

The nominated contact person and contact details should refer to a person able to answer questions regarding the application whilst it is being prepared and assessed and once the grant has been awarded. If the nominated contact person changes, please notify Bio Innovation SA immediately.

5.2 Part 2 – The Project

A. Project Title

The project title should be a short, single sentence which, if a grant is awarded, may be used for reference purposes and in promotional activities relating to the BDI.

B. Company Profile

In this section, provide some background on the company or the formation of the new company (if not yet formed): the reason it was/is being formed; how and when it was/will be formed; and who formed/will form the company.

C. Summary of Project

In a few sentences, describe what the project is about. Broadly outline the activities to be undertaken and their significance to the company and include the likely project outcomes and benefits (this information must be non-technical and **non-confidential** and may be used by Bio Innovation SA in promotional activities relating to the BDI if the project is approved for funding). Please keep this section brief and do not include confidential information.

D. Detail of Activities and Milestones

In this section applicants should detail:

- i) the proposed activities (including the estimated costs);
- ii) the individuals and/or organisations who will conduct the proposed activities; and
- iii) the anticipated completion times of key milestones from a nominated starting date.

Attach a copy of any quotes for the activities for which you are requesting funds. You may be asked to justify these costs. If you need to access equipment and facilities, you will need to provide evidence that you have obtained agreement to use these. Please note that BDI funds cannot be used to pay staff salaries and major equipment. The information in this section should be summarised in the form of a list or table. Applicants should note that the dates provided (a commencement date, the expected completion dates of key milestones and a project completion date) will be included in the grant deed and will be used to monitor the progress of the project.

E. Significance of Activities

This is the section where applicants should provide detail on the significance of the activities to the company and why they are critical to its success. For example, the significance of obtaining legal advice might be to enable the company to in-license intellectual property from another party, enabling the achievement of certain commercial milestones. This section also needs to address Merit Criteria a and d (Section 3) and to provide reasons why the application should be approved.

F. Intellectual Property

Applicants must summarise their intellectual property position and list any patents (pending or granted applications) or other forms of registrable intellectual property of relevance. This section should outline how intellectual property resulting from the project/activities will be protected for the benefit of the Applicant.

G. Market Potential

This section should be used to describe the market (existing and future) for the potential product and its competitive advantage. It should identify such things as the unmet market need, market size (in dollars), estimates of market penetration (in numbers of patients/treatments/tests/etc), current practice, efficacy of current treatment(s), competitive products in development, likely changes in the patient/customer demographics, and any other relevant information.

H. Summary of Commercialisation Plan

Applicants must provide a brief summary of the commercialisation plan for their technology and how the project/activities contribute to that plan. Outline any risks you have identified in your commercialisation plan and how you intend to mitigate those risks. This section would usually include the business strategy and plans for future funding, facilities etc. and allows applicants to substantiate that they can meet Merit Criteria a, b and d (Section 3).

I. Management Capabilities

The likelihood of success of a company is influenced greatly by its management capabilities. In this section applicants need to provide a brief description of the management team and the Board and any key advisors. Include formal qualifications, previous experience and commercial expertise. Are there gaps in the current management team that need to be addressed? If so, how and when are these gaps being addressed. This section allows applicants to address Merit Criteria a and b (Section 3). Curriculum vitae for the team are not necessary at this stage but they may be requested by Bio Innovation SA during the assessment process.

J. Benefits to South Australia

State how the commercialisation of research outcomes will benefit South Australia and meet Merit Criterion d (Section 3). These could include opportunities for employment, investment attraction and income generation, and/or possible synergies with other South Australian research organisations or bioscience companies.

K. Request for Funding and Detailed Budget

In this section applicants should provide a detailed budget of what the funds are to be used for and when they are required. Be sure to include a total of the amount of funding that you are requesting. Please note:

- the maximum amount available for a BDI grant is \$250,000 + GST; and
- the grant must be spent within one year of being awarded or as agreed with Bio Innovation SA.

It is important to note that if the grant is awarded, the funds can only be used for the activities described in the Detail of Activities section of the Application Form

and approved expenditure will be paid either in arrears or upfront. If the cost of the activities is less than estimated, the unspent funds will be retained by Bio Innovation SA.

L. Need for Financial Assistance

In order to address Merit Criteria c (Section 3), applicants must be able to demonstrate a genuine need for the funding. Explain why your project will not proceed satisfactorily without a grant? What would be the impact of not receiving funding for this project? Where a company has been formed and is more than 3 months old, a Profit & Loss Statement and Balance Sheet must be provided. All applicants must provide information on their current financial position to verify the need for funding.

Applicants will also need to provide details of any funding for the eligible activities or similar activities for which they have applied previously or intend to apply. Although Bio Innovation SA will not fund activities that are funded by other means (eg. other grants, contracts, etc), applicants are encouraged to apply for funding from other organisations, such as AusIndustry, for related activities. Applicants that are seeking other grants for related activities will be viewed favourably and requests for assistance with the preparation of other grants are welcomed.

5.3 Part 3 – Declaration

Please read the declaration carefully before signing.

6 The Selection Process

6.1 Assessment of Grants

Applications for grants under the BDI will be assessed by Bio Innovation SA in the context of the Merit Criteria (Section 3). Bio Innovation SA reserves the right not to fund any applications under the BDI regardless of whether an applicant company fulfils the eligibility requirements and addresses all Merit Criteria.

6.2 Successful Applications

Successful applicants will be notified in writing and will be required to enter into a Grant Deed with Bio Innovation SA for the funding.

There is a finite pool of funding available each financial year for the BDI, thus Bio Innovation SA may change the timing of grant payment to enable it to maintain cash flows within the Initiative annual budget. Grant recipients will be notified of any changes in writing.

6.3 Reporting Requirements

Reporting requirements will be specific to each BDI grant and should be discussed during meetings with Bio Innovation SA before the application is submitted. In addition, every BDI recipient will be required to provide a report on the outcomes of the grant one year from the date of completion. The reporting requirements will be set out in the Grant Deed.

6.4 Unsuccessful Applications

Unsuccessful applicants will be notified in writing. Unsuccessful applications can be resubmitted for assessment. However, it should be noted that Bio Innovation SA may refuse an application if:

- a) the application is the same, or substantially the same, as any previous application that was not accepted by Bio Innovation SA; or
- b) the applicant has already made more than one application for which Bio Innovation SA has decided not to grant financial assistance.

6.5 Confidentiality and Conflicts of Interest

Protecting applicants' confidential information is important to Bio Innovation SA. Information provided by applicants will be considered confidential and treated as such by Bio Innovation SA staff and any third parties from whom advice is sought. Confidential information will only be released with the applicant's agreement or where required by law.

All Bio Innovation SA staff, Board members, and third parties from whom advice is sought regarding applications, will be required to declare any conflict of interest before having access to confidential material. Where a conflict of interest exists, the Chief Executive of Bio Innovation SA will take appropriate action. Bio Innovation SA will sign a confidentiality agreement if required.

Following approval by Bio Innovation SA, the broad details of successful applications, such as, the name of the recipient, the amount of funding and a brief explanation of the project taken from the Summary of Activities section of the Application Form, may be disclosed for the purposes of promoting the BDI and reporting on its operation.

7 Contact Us

If applicants think they may be eligible for assistance under the BDI, they should contact Bio Innovation SA.

Bio Innovation SA is located at Level 15, 33 King William Street, Adelaide, SA, 5000. Applicants can find more information on Bio Innovation SA's website at www.bioinnovationsa.com.au or by calling Bio Innovation SA on (08) 8217 6400.