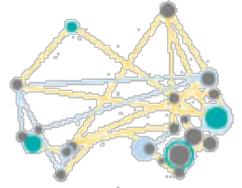




Biomedical
TRANSLATION BRIDGE
PROGRAM

Powered by



MTPConnect
MedTech and Pharma Growth Centre

In partnership with



UNIQUEST



Biomedical Translation Bridge (BTB) Program

FREQUENTLY ASKED QUESTIONS



Australian Government
Department of Industry,
Innovation and Science

Industry
Growth
Centres



Australian Government
Department of Health
Medical Research Future Fund

Frequently Asked Questions

What is the Biomedical Translation Bridge Program

The \$22.3 million Biomedical Translation Bridge (BTB) program is an initiative of the Medical Research Future Fund (MRFF). The BTB program will identify and develop high quality, early stage projects and support their translation to proof of concept stage. The projects will lead to new therapies, technologies, medical devices and preventative interventions to improve the health of Australians. They will also generate commercial returns, helping create the high paying jobs of the future and drive economic growth in Australia.

The BTB program is led by MTPConnect, the Medical Technologies and Pharmaceuticals (MTP) Industry Growth Centre, in partnership with BioCurate (University of Melbourne and Monash University), UniQuest (University of Queensland through its drug discovery initiative QEDDI), the Medical Device Partnering Program (MDPP, led by Flinders University) and the Bridge and BridgeTech program (through the Queensland University of Technology).

What is MTPConnect?

MTPConnect is the Industry Growth Centre for the medical technology, biotechnology and pharmaceutical sector. As an independent, not-for-profit organisation MTPConnect champions a sector-led approach to accelerating the growth of Australia's MTP sector.

Since establishment in November 2015, MTPConnect has significantly impacted the MTP sector by delivering Strategic Funding to key initiatives, undertaking Direct Action and being the trusted and Independent Voice to inform government on key issues, challenges and opportunities.

Through the Department of Industry, Innovation and Science's Growth Centre Project Fund, MTPConnect has committed \$15.6 million across 36 collaborative projects, engaging over 160 consortium members and leveraging \$22 million of matched cash funding from industry.

In addition to the BTB program, MTPConnect also operates the MRFF's BioMedTech Horizons program which currently supports 11 projects and will deploy an additional \$35 million over the next three years.

What is BioCurate?

BioCurate is an independently operated joint venture of the University of Melbourne and Monash University, supported by the Victorian State Government. The Board is independently chaired by The Hon John Brumby AO with CEO Dr C. Glenn Begley leading a team of industry-experienced commercial scientists and professional staff.

BioCurate aims to be a recognised global leader in the translation of basic medical research into human therapeutics. The Company offers a new model, designed to address the key challenges that limit the translation and commercialisation of biomedical and pharmaceutical research everywhere. Its purpose is to increase the clinical impact and patient benefit from research, via either the commercial or public good route.

What is UniQuest and QEDDI?

UniQuest is a leading university-based commercialisation office, managing the intellectual property of The University of Queensland. Since 1984, it has created more than 100 start-ups based on UQ research and raised more than \$700 million. UniQuest benchmarks in the top five per cent globally for university commercialisation, generating more licence income than the other Group of Eight universities.

UniQuest manages an extensive intellectual property portfolio, including the HPV vaccine Gardasil. Gross sales of products licensed by UniQuest have surpassed \$US16 billion. More than \$465 million in revenue has been returned to UQ.

The Queensland Emory Drug Discovery Initiative (QEDDI), a division of UniQuest, is a small molecule drug discovery and development facility translating The University of Queensland's biomedical research into new medicines to deliver faster health benefits. QEDDI will translate drug target biology or small molecule hits/leads into lead molecules/drug candidates using medicinal chemistry with the ultimate aim of a commercial outcome. By advancing academic research to novel molecules it is expected to increase the probability of the research striking a commercialisation partnership at increased commercial terms.

What is the Medical Device Partnering Program?

The Medical Device Partnering Program (MDPP) is an ideas incubator driving entrepreneurial culture within the medtech sector. MDPP fosters collaborations between researchers, industry, end-users and government and develops novel medical devices with global market potential.

MDPP forms the essential links between clinical need and knowledge with technical expertise and industry know how. As such, the program is a key enabler for the sector, building the bridge to connect bench to bedside and supporting ideas to the proof-of-concept and prototypes that are required to drive engagement with industry and end users. MDPP is a national initiative working closely with more than 30 partners across Australia, including research organisations, health networks, accelerators, service providers and funding bodies.

What are the Bridge and BridgeTech Programs?

The Bridge and BridgeTech Programs, facilitated and hosted by QUT, are nation-wide collaborative commercialisation training programs.

The Bridge program provides commercialisation training focused on the pharmaceutical sector in collaboration with 10 University and pharmaceutical industry partners. Now in its third year, Bridge selects up to 100 participants each year from around Australia.

The BridgeTech program provides industry focused commercialisation training for the medtech-medical devices sector in collaboration with 20 university and industry sector partners. Now in its second year, BridgeTech selects up to 80 participants annually to focus on training for the medical technology, devices and diagnostic industries.

Both programs aim to improve the skills and capabilities of Australia's life science entrepreneurs, researchers and scientists, to improve the quality and quantity of commercial deals and deepen collaboration between Australian researchers and the relevant industry sectors.

Offerings and Focus

Does the BTB Program have a disease focus?

The BTB Program is agnostic as to human disease area and will accept applications that address all disease areas and any therapeutic modality. We will however have a focus on disease areas of commercial interest and projects that have clear points of differentiation from anything similar in development or on the market.

Does the Program focus on specific therapeutic modalities?

The BTB Program is agnostic as to therapeutic modality and will accept applications that address all therapeutic modalities.

What type of projects are funded?

BTB will fund research and development projects to progress novel therapeutics or medical devices to achieve Proof of Concept. There must be a clear value proposition for the proposed product and differentiating features from currently available solutions.

What definition is used for medical devices?

All kinds of medical devices are eligible under the BTB including hospital equipment, surgical instrumentation, implantables, diagnostic devices, therapeutic devices, assistive technologies, clinic software, personal devices and apps, and medical simulators. However, a preference is given to those that meet the definition and are regulated under the Therapeutic Goods Administration. BTB accepts applications for technologies at Technology Readiness Levels 2 – 7. We require evidence of research that clearly identifies the problem or the possibility of the technological solution.

What projects are out of scope for the BTB Program?

Databases and non-human health programs. Ideas alone are not accepted by the BTB. There must be evidence of research that has been undertaken that validates the problem or the potential of the technology.

How does the BTB panel decide on what projects to fund?

Expressions of Interest and Second Stage Applications that meet the eligibility criteria set out in the Program Guidelines (insert link) will be assessed by an expert review panel against defined selection criteria that address several technical, financial and commercial factors.

The projects will need to be commercially attractive and demonstrate a good probability of leading to a commercial outcome such as a licence deal, research/option deal, investment via the formation of a start-up company with VC funding or public good outcome. Projects will need to provide clear differentiation from the standard of care.

Selection criteria

Where do I find the selection criteria?

The Selection Criteria for all projects are detailed in the Program Guidelines which can be found on the [MTPConnect website](#).

Are the Selection Criteria applicable to all eligible projects and will they be published on the website?

The Selection Criteria and Program Guidelines are detailed at the [BTB page](#) on the [MTPConnect website](#). Selection criteria may vary slightly according to therapeutic modality and application (medtech, biotech or pharmaceutical).

What is a willing inventor or lead investigator?

A 'willing inventor' is one who is willing to participate in mentorship and engage constructively with the advice and support process provided by the BTB venture partners.

What does robust data mean?

Experimental, ideally randomised, blinded and controlled (positive, negative) with standard of care comparator where possible. Ideally reproducible at independent site or your own data. Projects should not be based purely on published, non-validated data.

Will this mechanism be biased towards mass or niche market needs?

The BTB Program is open to applications that address any disease state and all therapeutic modalities/market needs. Applications will be assessed based on strength of application according to selection criteria.

Will you consider opportunities that repurpose existing drugs?

The BTB Program is designed to support opportunities that lead to commercial outcomes. Opportunities that repurpose known drugs will only be considered when a viable Intellectual Property plan can be demonstrated. Applicants seeking support for drug repurposing are encouraged to contact MTPConnect before completing an application.

What does the BTB Program consider Proof of Concept?

The BTB Program is designed to help progress opportunities to the point where they are able to attract investment from venture capital or secure a commercial outcome/partner.

Will the BTB Program support opportunities addressing rare diseases?

Opportunities that address rare diseases are often very attractive to biotech and pharmaceutical companies. The BTB Program will support strong applications that address rare diseases.

Does the unmet medical need have to be Australian? Does it have to have commercial return?

All markets will have commercial return, but the end market the BTB is concentrating on is the next funding market (e.g. pharma or venture capital etc.). The unmet medical need does not have to be Australian.

Would a device used to deliver a drug be considered for the BTB program?

If the device is used to deliver the drug, it is not a medtech project. For injection or membrane devices, we can help you. Combo drug/device are in scope.

Eligibility Criteria

Where do I find the eligibility criteria?

The Eligibility Criteria are detailed within the Program Guidelines and can be found at the [BTB website](#).

Who can apply?

Entities eligible for funding under the BTB Program are defined in s24 of the [Medical Research Future Fund Act 2015](#) and include:

- a medical research institute;
- a university;
- a corporate Commonwealth entity;
- a corporation.

Applicants must have an Australian Business Number (ABN).

I have a spin-out company with seed funding and previously invested capital. If our application is accepted, are the expenses we have already incurred viewed as eligible expenses or as matching contributions?

No, expenses must be incurred during the tenure of the grant.

Can a multinational company be a partner of an Australian applicant?

Multinational companies can be partners in an application with an eligible Australian entity. Matching funding can come from any source provided it does not come from a government-funded program.

Do the projects have to be submitted through an institution or solely through an SME or could it be both?

It can be any of the above. The SME or institution must have matching funding.

Expressions of Interest (EOI)

Where do I find the EOI form?

Application of an EOI must be made online through the [BTB page](#) on the [MTPConnect website](#).

How will EOIs be matched with UniQuest, BioCurate or MDPP?

Eligible EOIs that are successful in passing through expert review will be matched with one of our three partners taking into account our partners' expertise and any previous interactions the applicants have had with one or more of our partners.

Can I submit an EOI for a project that I have already submitted as an application to another granting body such as the NHMRC or to another government funding source?

The BTB Program will accept applications for projects that have already been submitted to other funding sources. However, BTB will not fund programs that are already funded by an alternative source. Should your application to an alternative funding source be successful, the BTB application/funding will be discontinued.

If unsuccessful in Round 1, can I resubmit in Round 2?

Unsuccessful applicants are encouraged to re-apply in subsequent rounds once you have adequately addressed any shortcomings identified by the review panels in previous applications.

Can big pharma be partners of the SME applicants?

The funding needs to be in cash and can come from big pharma coming through eligible entities. The IP would need to reside with the applicant, which would not be the big pharma partner.

What would the ranking of projects look like?

Projects with more validation will be ranked higher and will likely to get more funding. However, there is opportunity to work with BioCurate/UniQuest/MDPP to get the application 'mentored' to make it more 'BTB ready'.

Can Venture Capital provide the matching funding?

Yes.

For Researchers and Faculty/Institutes

How to propose projects?

EOI calls will be made twice yearly (January and July).

Potential applicants are encouraged to discuss potential applications with MTPConnect, BioCurate, UniQuest or MDPP at any time throughout the year. In addition, applications should be discussed with the relevant technology transfer office/business development group of the applicant prior to submission.

Funding

How much funding is available for my project?

Successful applicants to the BTB Program can receive up to \$1 million of matching funding over a period of up to two years. Applicants will be required to provide one-to-one matching funding (cash) to be eligible.

Can any of the funds be spent overseas or do they need to be spent in Australia?

Funding from the BTB Program must be spent in Australia. However, overseas expenditures may be approved on a case-by-case basis where applicants can clearly demonstrate that the specific expertise or activity required to progress a project can't be accessed or completed from within Australia.

I don't have the matching funding now, but I am confident that I will have it soon. Am I eligible for the BTB program?

Applicants are required to demonstrate that they have matching funding before their project begins. Payments from the BTB program are paid in arrears upon achieving defined and agreed milestones. Applicants must demonstrate that they have contributed an equal or greater amount of funding within each milestone.

If I have government funding as matching funding am I eligible?

No. You will need matched funding outside of any existing government funding. Universities, MRIs and foundations may contribute matching funding from non-government sources of revenue.

Can international grants be considered as matched funding?

On a case by case basis. International capital source is eligible.

Is crowd funding/family and friend's investment considered matching funding?

Yes, all non-government sources of matching cash are acceptable. However, programs will be assessed based upon their ability to secure adequate matching capital.

At what point is matching funding required?

A strong and viable plan for matched funding should be indicated in the EOI. Stage 2 applications will require a formal letter of commitment.

Can I change sources of matching funding during the Program?

This would be assessed on a case by case basis.

What evidence of matching funding do I need to provide?

Funding is paid in arrears. Successful applicants will need to provide copies of receipts for eligible expenditures before the BTB Program can make payments.

Is there a time period for which money has to be spent if awarded?

The projects should run for two years.

What range of investment will likely be awarded?

\$200,000 to \$1 million – matched.

Intellectual Property Management and Commercialisation

How will Intellectual Property be protected during the application and funding process?

EOIs are made on a non-confidential basis and should not contain any enabling data or material. MTPConnect and its partners will enter into a Confidentiality Disclosure Agreement with applicants whose projects move beyond the EOI stage to allow for a complete review and assessment of your project.

Who owns the Intellectual Property?

All IP related to the project defined in the EOI and full application is owned by the applicant, subject to any arrangements it has with 3rd parties (eg. CROs). If the MTPConnect or its partners creates IP as part of the proposal review or mentorship process, the IP will be owned by the applicant. Inventorship will be determined based on standard protocols.

If IP is generated as part of a funded project that is saleable to an overseas interest, would that be permitted?

Yes.

Who pays for patent applications?

Patenting/protection of the IP will be the responsibility of the successful applicant.

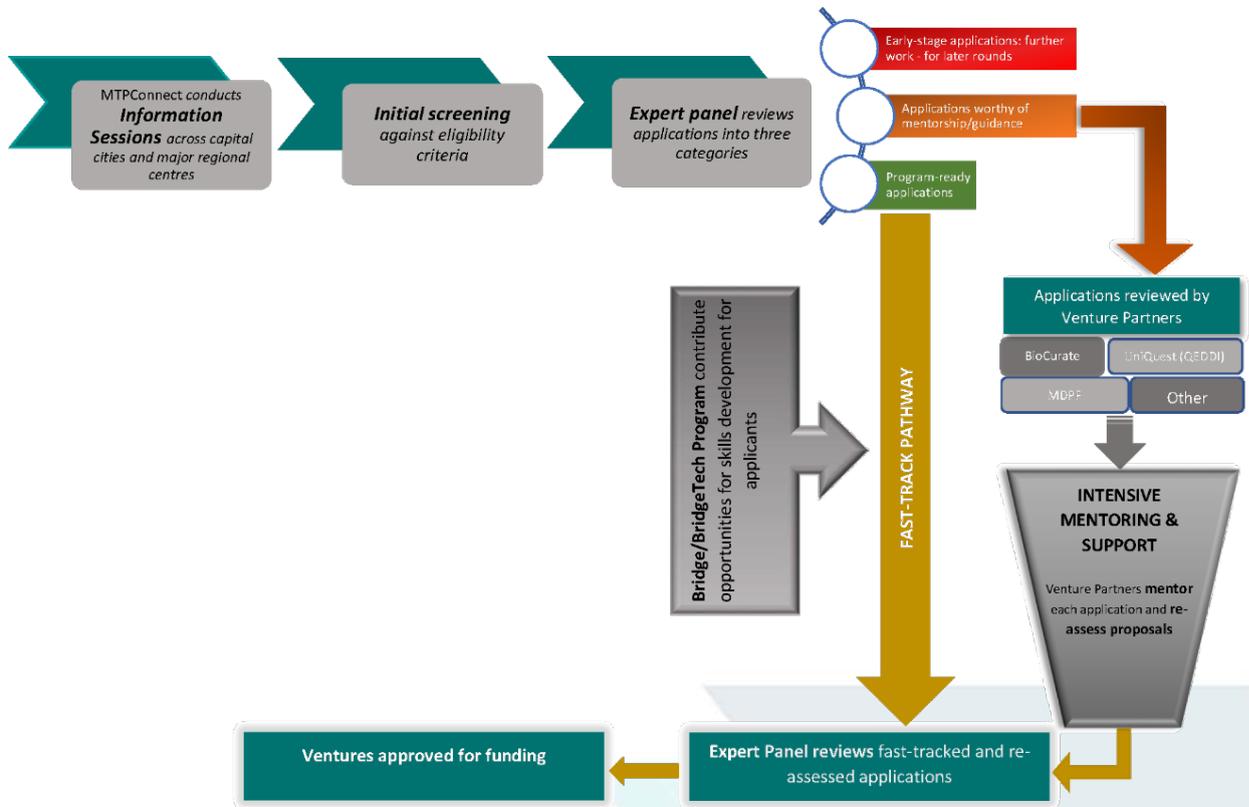
What happens to my project when it has received the maximum BTB funding but still requires further development and funding?

The BTB Program can provide up to \$1 million of matching funding over a two-year period. Upon completion of the program, applicants must seek other sources of funding.

Will MTPConnect and/or venture partner require a return on BTB investment?

No. Any venture partner involvement is on a service basis and any requirement for return on subsequent investment after the end of the funding period will be negotiated outside of the BTB mechanism.

How the project will be assessed in the BTB program?



Connecting with the BTB Team

Further questions can be directed to: Danielle Shand, BTB Operations and Events Manager:
Danielle.Shand@mtpconnect.org.au.

Check the [BTB website](#) for updates.