Biomedical Translation Bridge Program (BTB) EOI
BTB EOI
Application BTB00196 From Australian National University
Form Submitted 15 Aug 2019, 11:43am AEST

BTB Application Process - Before you begin

* indicates a required field

Key Points

- The Biomedical Translation Bridge program aims to nurture early stage health and medical research ventures to reach proof-of-concept stage with potential to attract further capital and support. EOIs need to clearly articulate clinical benefit to patients and an advantageous point of differentiation from anything similar on the market or in development.
- EOIs will be prioritised based on commercial and scientific selection criteria. There will be preliminary commercial due diligence undertaken on the proposal to address the commercial selection criteria. In all cases, feedback will be provided to the applicant(s).
- Successful EOIs will progress to a full proposal which will be collaboratively prepared by BTB Venture Partners and the applicants. The proposals will be reviewed by an independent panel which will make recommendations for selection. Projects will then be selected to enter the BTB pipeline. In all cases, feedback will be provided to the applicant(s).
- Successful applications to enter the BTB pipeline will be worked up into a project plan, which will include resourcing, timelines, key decision points for project progression and go/no go criteria. Projects will be run collaboratively with the applicants and will be subject to regular review against the pre-determined and agreed milestones.

Completing this Form

- Please do not use abbreviations unless fully explained.
- Where any data is provided to support the EOI, please indicate if this is from your own research, or from another research group or existing literature reports.
- Where answers to specific questions are not known, please state not known at this stage.
- Please complete as many of the relevant sections as possible with those marked with a Asterix (*) being required.
- **It is required that this EOI form be completed in conjunction with the Institutional Business Development/Technology Transfer Office.**
- For assistance in completing the EOI, please contact:
    - MTPConnect via BTB@mtpconnect.org.au
- EOI submission close on Friday 16 August 2019 at 17.00pm AEST. Late applications will not be accepted.

Disclaimer/Declaration

I am authorised on behalf of the applicant to submit this application and that the information in this application and attachments is to the best of my knowledge true and correct. I will notify MTPConnect of any changes to this information and any circumstances that may affect this application. I acknowledge that MTPConnect may refer this application to external experts or other Government Departments for assessment, reporting, advice, comment or for discussions regarding alternative or collaborative grant funding opportunities.

I understand that MTPConnect may be subject to Freedom of Information (FOI) requests and that if such a request is made, MTPConnect will consult with the applicant before any decision is made to release the application or supporting documentation.

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I acknowledge and agree that this application does not contain confidential information and will not be treated as confidential by MTPConnect. Accordingly, MTPConnect may publish and disclose the contents of this application.

I understand that this is an application only and may not necessarily result in funding approval. Shortlisted applications will be subject to a further round of submission and review and any subsequent funding offers will be subject to MTPConnect receipt of funding and standard grant agreement.

I have read and agree to the above *
◉ Yes ○ No

Applicant Details

* indicates a required field

Applicant Name

Name *
Prof Ted Maddess

Position

Position *
Professor of Neuroscience

Organisation Details

Please enter the organisations details in this section.

Organisation Name *
Australian National University

Organisation ABN *
52 234 063 906

Information from the Australian Business Register	
ABN	52 234 063 906
Entity name	Australian National University
ABN status	Active
Entity type	Other Incorporated Entity
Goods & Services Tax (GST)	Yes
DGR Endorsed	Yes (Item 1)
ATO Charity Type	Charity More information
ACNC Registration	Registered
Tax Concessions	GST Concession, Income Tax Exemption
Main business location	2601 ACT

Information retrieved at 11:41am today
Must be an ABN.

Organisation Address *
131 Garran Road
Australian National University (JCSMR)
Acton ACT 2600 Australia

Address Line 1, Suburb/Town, State/Province, Postcode, and Country are required.

Organisation Postal Address *
131 Garran Road
Australian National University (JCSMR)
Acton ACT 2600 Australia
Address Line 1, Suburb/Town, State/Province, Postcode, and Country are required.

Email *
ted.maddess@anu.edu.au
Must be an email address.

Phone Number *
0411 443 415
Must be an Australian phone number.

Organisation Website
https://www.anu.edu.au/
Must be a URL.

Project Details

* indicates a required field

Research Team including any collaborating organisations

Please name key researchers (including collaborators, consultants) involved in your application or proposed project.

Name and Position	Organisation	Any other affiliations (please list all)	Email
Prof Ted Maddess	ANU, John Curtin School of Medical Research		ted.maddess@anu.edu.au
Prof Christopher Nolan	ANU, John Curtin School of Medical Research	The Canberra Hospital, Diabetes	christopher.nolan@anu.edu.au
Prof Christian Lueck	ANU, John Curtin School of Medical Research	The Canberra Hospital, Neurology	Christian.Lueck@act.gov.au
Assoc Prof Rohan Essex	ANU, John Curtin School of Medical Research	The Canberra Hospital, Ophthalmology	Rohan.Essex@act.gov.au
Assoc Prof Hanna Suominen	ANU, Computer Science	CSIRO, Data61	hanna.suominen@anu.edu.au
Dr Corinne Carle	ANU, John Curtin School of Medical Research		corinne.carle@anu.edu.au
Dr Josh van Kleef	ANU, John Curtin School of Medical Research		joshua.vankleef@anu.edu.au
Dr Faran Sabeti	U Canberra, Optometry	ANU, John Curtin School of Medical Research	Faran.Sabeti@canberra.edu.au
			Must be an email address.

Non-Confidential Summary of the Opportunity

Please provide a non-confidential summary of the project and applicant to be used for publicity purposes. *
Testing of the peripheral visual fields is critical to diagnosing and managing a broad range of eye and brain disorders. Until now such tests involved patients responding to hundreds of presentations of difficult-to-see visual stimuli. Consequently the tests were slow, tedious, and poorly reproducible. Now a group at the Australian National University and University of Canberra have worked with Konan Medical Inc to produce a simple, objective, peripheral vision test that requires no subject responses. Instead it uses tiny responses of the pupils to objectively test 88 parts of both eyes at the same time. The present project involves even newer versions that take just 80 seconds to test both eyes. The group leader, Prof Ted Maddess, has previously commercialised a very successful visual field test and for that won Australia's highest prize for applied research: the Clunies Ross Award.
Must be no more than 150 words.

Do you provide consent for MTPConnect and it's BTB Venture Partners to present the information contained in the non-confidential summary to other industry

partners (e.g. biotech and pharma companies) who may have an interest in providing the matching funding for your opportunity? *
◉ Yes ○ No

Eligibility Criteria

Medical Research Future Fund Act 2015 (https://www.legislation.gov.au/Details/C2019C00079).

Is the organisation applying an Australian enterprise and MRFF eligible organisation? *
◉ Yes ○ No

Have you, or are you able to, provide the required matching cash contribution? *
◉ Yes ○ No

Brief details of the source of the matching cash contribution, if available.
The matching cash comes from two sources: 50% from the Australian National University through its Our Health in Our Hands (OHIOH) Grand Challenge initiative, and 50% from our commercial partner Konan Medical USA.
Must be no more than 100 words.

Project Specific Questions

* indicates a required field

Please select your project area

◉ Click here for Medical Device Projects
○ Click here for Therapeutics Projects

For Medical devices Projects:

Project Title *
Rapid, objective eye and brain testing

Product Description (Provide a short description of the proposed product) *
Our prototype objectiveFIELD Analyser (OFA) is a non-contact form of visual-field test or “pe rimeter”. Perimeters map losses of sensitivity to light at many locations of the peripheral vis ual field. Various diseases produce characteristic patterns of visual field loss. Current perime ters operate by patients making 500+ button presses/eye to sequences of individually prese nted light stimuli. Consequently these tests are subjective, slow and poorly reproducible. Th e OFA objectively maps the visual fields of both eyes by concurrently presenting 11 stimuli/s /eye and monitoring videoed responses of the two pupils in real time. Previously unavailable response delay and other brain-function data are also obtained.
Provide a short description (100 words recommended) of your product - what are you out to do?

Choose Stage of Development

Medical Devices *
- ○ Idea
- ○ Proof of Concept
- ◉ Prototype
- ○ Available on Market

Value Proposition

Describe the value proposition.

Why will your product be purchased? What problem will it solve? *
The current OFA device is at an advanced pre-production prototype stage. It is being developed by the group's commercial partner: Konan Medical, an ophthalmic device manufacturer. The OFA is based upon our 4 patent families and has FDA clearance in the USA.

The current prototype is a small desktop device (https://konanmedical.com/objectiveFIELD/). One can use the touchscreen interface, or optionally add a wireless mouse and keyboard. Including set-up time and short breaks for the patients, the current OFA tests take about 7 minutes to produce an ophthalmic industry-standard 30-2 report for each eye. Standard perimeters take nearly 7 minutes to provide a 30-2 report for just one eye. In assessing both eyes simultaneously the OFA can make sensitive comparisons between eyes. It is also highly reproducible. The OFA has normative data-bases for three 7-minute tests. These include two wide-field tests for diseases like glaucoma, and a central-field (macular) test for retinal diseases like macular degeneration and diabetic retinopathy. The developers at the Australian National University (ANU) have 22 publications supporting the ophthalmic utility of the OFA. The OFA has also been shown to have value in migraine, epilepsy, stroke, multiple-sclerosis, and concussion.

The ANU teams recently created 3 new tests that run in 80-seconds. These can run on the desktop but are targeted at more portable devices. The overarching concept is to provide lower-cost devices to broader range of health professionals. The specific proposal is to fund further clinical-validation studies of the new 80-second tests and then to create normative data-bases.

Must be no more than 250 words.

Customer

Describe the customer experience.

How, when and where will the end-user / customer use the product? *
Perimeters are used in ophthalmic and neurological examinations for eye- and brain-related issues. Different eye/brain conditions manifest as characteristic patterns of vision loss across the peripheral visual field and typically don't affect central reading vision.

Current perimeters make patients stare straight ahead for between 5 and 15 minutes and then press a button 500+ times when they think they see a small visual stimulus. This is then repeated for the other eye. The test stimuli are deliberately made difficult to see. Given their subjective nature the reproducibility of these tests is very poor. About 10% to 15% patients fail the test and need to repeat it. Almost everyone hates doing these tests.

With the OFA the patients look at what appears to be a display screen. They don't notice that they are seeing two displays, one for each eye. Separate stimuli are delivered to each eye at 11/second/eye. The stimuli occur at random all over the field, and any one

region only sees a stimulus every 4 seconds. They look a bit like snowflakes landing on a windscreen and do not evoke migraines or epileptic-seizures as confirmed by safety studies. The OFA is objective so patients just watch passively. They love it. The 7-minute stimuli the test is broken into 9 segments of 40 seconds duration with interleaved breaks. The eye/brain responses for stimulation of both eyes are calculated from the pupil responses that are monitored by infrared video cameras. Completely novel data on eye/brain response delays is also obtained.

Must be no more than 250 words.

Target Market & Size

Provide details of the target market and its size.

Who are the end-users or direct purchasers of the product? Which markets do you intend to target globally, and how large are the end-user groups? If available, provide a forecast of sales. *

Our patent position means that no similar technologies are being developed. The group has made a formal disclosure to the ANU of the basis for a new patent. That will boost the performance of all OFA tests, new and old. The perimetry market is currently dominated by ophthalmologists and optometrists managing glaucoma. That is about a $200 million p.a. market. Damage to the eyes by diseases like diabetes and age-related macular degeneration (AMD) is managed by ophthalmologists referred to as retinal specialists. Glaucoma, AMD and diabetic eye damage are the three largest sources of blindness. There are 4-times more AMD and diabetic eye disease patients than glaucoma patients. Until recently retinal specialists tended not to use perimetry. That is changing however due to the advent of so-called micro-perimeters, which have begun to be taken up by those practitioners. The OFA shares features of microperimeters including eye tracking. Like standard perimeters, however, micro-perimeters use behavioural testing and so are slow and poorly reproducible. One of the new 80-second tests assesses the same parts of the visual field as microperimeters, and does so with stimuli that provide much better compatibility with output from another common modern ophthalmic tool: optical coherence tomography. The OFA is also useful in neurological diseases (see above). The scope for a much larger market than glaucoma is significant.

Must be no more than 250 words.

Competitors

List the competing products. *

The market leaders (80%) in standard perimeters are Carl Zeiss Meditec (USA), with their Humphrey Field Analyser 3, and Haag Streit (Switzerland) with their Octopus 900. Carl Zeiss also sell the Matrix perimeter invented by the project leader Prof Maddess. A variety of other companies sell small numbers of units. The micro-perimeter market is dominated by Nidek (Japan) with their MP3, and the Maia manufactured by Centrevue (Italy). Three groups in Israel, Germany and Japan are examining pupil driven perimetry, but like standard perimetry their stimuli are presented one at a time and so the tests are slow and have relatively few repeats within a test. The ANU group uses patented “multifocal” methods to present many stimuli concurrently. For example during the 7-minute OFA tests each of the 44 regions per eye are tested 90 times, producing accurate and reproducible results. The Israeli group has in the past incorrectly claimed that their method is multifocal. Thanks to intervention by the ANU group they no-longer do so.

Must be no more than 250 words.

Commercial Potential

* indicates a required field

Commercialisation Strategy

Explain the commercialisation strategy.

What is your commercialisation strategy after completion of the BTB project? e.g. Have you established or intend to establish a company? Do you intend to license your innovation, seek investment or enter into a partnership? *
Aside from creating and marketing ophthalmic instruments our commercial partner, Konan Medical, has another substantial business: providing advice to medical instrument companies about the new FDA regulations. The recent changes to those rules make Konan an ideal partner as well as an excellent route to market. Sales of the desktop unit are designed to begin in October 2019. Initially the plan is to allow that process to seed interest in the device. The resulting pool of OFA desktops in the field provides an excellent vehicle for the introduction of the new 80-second tests, which would be a software upgrade on the existing devices.

Following the initial roll-out onto the desktop devices in the field Konan plan to introduce more portable, lower-cost devices to target a wider market of health professionals, possibly including GPs and pharmacists. Substantial design work has been done on portable units, which will be the size of smaller virtual/augmented reality systems.

Before that however the demonstration of the clinical utility of the new tests, and the subsequent production of normative databases for the new tests is required, and those are the main purposes of this project. The ANU group has preliminary normative data now, including reproducibility data, and has begun testing in Type-1 diabetes, early-stage AMD, MS, and concussion with promising preliminary results, and these agree with the published outcomes of the original 7-minute tests. Some changes to the current FDA 510k clearance will be required, but given their experience Konan are confident that is manageable.

Must be no more than 250 words.

Intellectual Property Strategy

Explain the IP strategy.

What IP protection do you have or intend to file (indicate any filed patents and their stage? If you have a patent, what are your patenting timelines? Do you control all of the IP rights to commercialise the project and if not please explain how you intend to secure them and list any freedom to operate (FTO) issues? *
The OFA is underpinned by 4 ANU patent families assigned under contract to Konan. Those patents are issued in the Australia, Canada, Europe, Japan and the USA. A critical patent is also issued in China. A new ANU patent application is in preparation. Therefore we control all of the IP and there are no FTO issues. Substantial research shows that the new patent will substantially improve the OFA devices, including both desktops and portables. It is also possible further IP will be developed during the proposed project. Overall the ANU team is very experienced at managing their IP. The ANU leader, Prof Ted Maddess has had 8 patents producing royalties including for a standard perimeter being sold by Carl Zeiss, which has grossed over $450 million. For that he won an ATSE Clunies Ross Award. He was made a Fellow of the (USA) National Academy of Inventors in 2018.

Must be no more than 150 words.

Development & Regulatory Requirements

What development and regulatory requirements will your product need to meet? In the case of medical devices, which regulatory classification does your product belong to?

Explain the development and regulatory requirements and any plans you already have in place. *
As mentioned, the OFA already has US FDA clearance. The commercial partner, Konan Medical, is expert in managing FDA approvals processes. Konan also has experience with approvals in Europe and other jurisdictions. Being a non-contact instrument the OFA it is a class 1 device. The 510k clearance deems that the OFA is substantially equivalent to the market leading Humphrey Field Analyser perimeter produced by Carl Zeiss Meditec, and also a commercially available pupillograph. The new portable devices would also be class 1 and may require a new clearance, but again Konan is an ideal partner for that.

Must be no more than 150 words.

Proposed Project

* indicates a required field

Project Title

(this section is to explain what the BTB funds would be used for)

Project Title *
Rapid, objective eye and brain testing

Short Description

Provide a short description of the proposed project. *
The project will have two phases: 1) clinical validation, and 2) normative data collection. Success with phase 1, based on data collected up to month 9, would be prerequisite for phase-2. Clinical validation will occur mostly in year 1, and will include some normative data collection, but some components will run through to the end of year two. Expanded normative data collection, from about 180 persons tested twice, will commence from year two. The clinical validation will occur on the new desktop prototypes supplied by Konan. Testing with portable prototypes provided by Konan will begin in late year 2.

Must be no more than 100 words.

Objectives

Provide the key objectives of the project. *
The clinical evaluations will cover diseases that have strong market interest, and for which we already have substantial data. That data includes published and unpublished clinical studies using current 7-minute tests, and preliminary data from the new 80-second tests from persons with MS, concussion, early-stage AMD, and Type-1 diabetes. These are done head-to-head with 7-minute tests and other ophthalmic tests including commercial

perimeters. We would continue that testing expanding to include glaucoma. Each study will include about 20 to 30 patients and age- and sex-matched normative data will be collected to examine diagnostic power. Short term reproducibility, related to the ability to track disease progression, will also be assessed. The phase-2 expanded normative testing will bring the numbers of normal control subjects in the OFA databases to 180/test, balanced across age and sex. Konan will begin fund independent validations of some studies, and manage regulatory approvals.

Must be no more than 150 words.

Project Partners

List any companies / individuals with an interest in the project and their role (e.g. partners, IP owners, manufacturer, distributor, designer).

Name	Role
Australian National University	Patentable IP, knowhow
Konan Medical USA Inc	Konan Medical is our key partner. We are working with the USA company but there is also a parent company, Konan Japan. Over time the Japanese company has become the smaller of the two. Konan are highly experienced at design, manufacture, and distribution of ophthalmic test devices. They are also expert in IP management and regulatory approvals.
Prof Ted Maddess	Patent inventor
Dr Andrew James	Patent inventor
Dr Corinne Carle	Patent inventor
Dr Joshua van Kleef	Researcher
Dr Faran Sabeti	Researcher

Indicative Budget

* indicates a required field

You have to show that you are able to provide the required matching cash

Funding Requested from BTB* (AUD$) *
$705,944.00
Total amount should not exceed more than AUD $1,000,000

Contributions

Identify the contributions to be made by partners.

Organisation	Cash	In-kind
ANU	$352,972.00	$525,188.00
Konan Medical USA Inc	$352,972.00	$665,000.00
	Must be a dollar amount.	Must be a dollar amount.

Totals

Total cash contribution *
$705,944.00
This number/amount is calculated.

Total cash In-kind contribution
$1,190,188.00
This number/amount is calculated.

Acknowledgement

* indicates a required field

Conflict of Interest

Do you have a conflict of interest *
◉ Yes ○ No

Please provide details of any conflicts of interest e.g. any professional, commercial and/or academic appointments, advisory positions and/or consultancy arrangements that may impact project selection, uptake, management and partnering/exit process. *
None of the applicants or partners has a conflict of interest that “may impact project selection, uptake, management and partnering/exit process”. Several of the research teams do stand to make royalty income from sales of any devices arising from the project. Those parties are Ted Maddess, Andrew James, Corinne Carle, Joshua van Kleef, and Faran Sabeti. We mention this in the interest of full disclosure.
Must be no more than 250 words.

Declaration

I am authorised on behalf of the applicant to submit this application and that the information in this application and attachments is to the best of my knowledge true and correct. I will notify MTPConnect of any changes to this information and any circumstances that may affect this application. I acknowledge that MTPConnect may refer this application to external experts or other Government Departments for assessment, reporting, advice, comment or for discussions regarding alternative or collaborative grant funding opportunities.

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I have read and agree to the above *
◉ Yes ○ No

Authorised Representative *
Ms Misha Hutchings

Position *
Assistant Manager, Research Management, Health & Medicine, The Australian National University

Phone Number *
(02) 6125 1761
Must be an Australian phone number.

Email *
misha.hutchings@anu.edu.au
Must be an email address.