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### **OVERVIEW**

- 1. The Biomedical Engineering Programme (BEP) is a competitive, multidisciplinary funding initiative aimed at supporting **clinically-driven MedTech innovations** with **promising commercialization potential**. The objective is to seed early MedTech innovations, which can in turn potentially contribute to a vibrant start-up ecosystem, and encourage value capture for the local innovation landscape.
- 2. Projects funded under BEP are required to take a needs-driven approach, and must be driven by a validated clinical need. Teams are expected to develop cost-effective technological solutions or innovations to address the identified clinical need, and demonstrate the value and effectiveness of the proposed tech solution in comparison to the current state-of-the-art and/or standard of care.
- 3. This user-centered approach to product development validates the end-user desirability, the technological feasibility and ultimately the economic viability, which is required for the technological solution to earn its place in the market. All funded projects must demonstrate high potential for commercial outcomes and show a high likelihood of deployment to impact patient care.







### **OVERVIEW**

- 4. The BEP encourages collaborative research projects with emphasis on regulated medical devices in its various forms. Drug/biomarker discovery research (small molecules and biologics) is not in the purview of this Call for Proposal. Refer to section on "Scope of MedTech" for a detailed description.
- 5. The BEP is geared to support MedTech projects in achieving **proof-of-concept** (i.e. TRL 2-4; refer to Annex for TRL description). Basic principles of the technology must have already been established and validated prior to the BEP. BEP-funded projects are not expected to complete clinical validation under the term of the BEP.
- 6. Some examples of expected project outcomes include technology deliverables like a lab prototype to illustrate the feasibility of the tech solution in addressing the clinical unmet need, as well as clinical deliverables such as clinical need validation, clinician focus group discussion, pre-clinical trial, pilot trial, comparison against the standard-of-care, etc. These examples are meant to be illustrative only and are not meant to be exhaustive.
- 7. Applications are **not restricted** to a particular clinical or technical area. Importantly, all proposals must show strong collaboration between the clinical and technical partners to solve a specific clinical need.







### **OVERVIEW**

- 8. Under BEP, Singapore Biodesign (SB) will be offering a **MedTech Training Workshop** specially catered to the shortlisted applicants. The workshop has been designed to equip potential shortlisted applicants with the Biodesign methodology (i.e. Identify, Invent, Implement) in MedTech Innovation. The goal of the workshop is to provide a guided hands-on and interactive session for project teams to spend dedicated time to deliberate and de-risk components of their project, ranging from the identification and validation of unmet healthcare needs, the development of novel technologies to address them, and the subsequent development of business and commercialization plans to bring them into patient care. The workshop is designed to help the teams with the drafting of the full proposal for BEP application.
- 9. For better understanding of the BEP, there will be virtual roadshows happening at the dates & times listed in the table below. This is a platform for you to also directly pose your queries related to the BEP Call for Proposals. Please register via the links provided for the specific session you wish to attend. The meeting link will be sent directly to your email.

BEP 2021 VIRTUAL ROADSHOW			
Date & Time	Registration Link		
5 July 2021, 12 – 1 PM	< https://zoom.us/webinar/register/WN_0kXjJy8NQOGT23yBkc9q9Q >		
19 July 2021, 12 – 1 PM	< https://zoom.us/webinar/register/WN_L0BbzQ60QQKbiENqhmrOxQ >		







### **SCOPE OF MEDTECH**

#### What is Medical Technology?

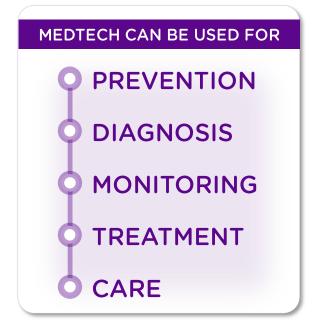
Medical technologies are products, services or solutions used to save and improve people's lives.

This can include the following:

- (i) <u>Devices</u>; defined as products which are used to diagnose, alleviate or treat a medical condition, e.g. X-ray machines, contact lenses, prosthetic knee implants measure or monitor functions of the body, e.g. blood pressure or blood sugar monitoring machines
- (ii) <u>In vitro diagnostics (IVDs)</u>; defined as **reagents, instruments, and systems** intended for use in the diagnosis of disease or other conditions.
- (iii) Software as a Medical Device (SaMD); defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device, e.g. telehealth, image analysis software, personalized medicine etc
- (iv) Digital health products; which includes categories such as mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine
- (v) Any combination of the above categories

This does not include (non-exhaustive):

- Pharmaceuticals such as small molecules, biologics, or otherwise other compounds which achieve its primary intended purposes through **chemical action** within or on the body of man or other animals and which is not dependent upon being **metabolized** for the achievement of its primary intended purposes
- Health and wellness products (without medical claims)
- Electronic health records system, or software to improve productivity of healthcare operations









## **BEP RUN 2 CALL FOR PROPOSAL DETAILS**

Call opens: 21st June 2021

**Apply via iGrants**: <a href="https://app.a-star.edu.sg/igrants/">https://app.a-star.edu.sg/igrants/</a>.

Application guidelines provided in Info Deck

#### **Deadline for LOI submission:**

30 July 2021

**Project Duration**: 12-18 Months

Funding Quantum: up to S\$500k/project<sup>1</sup>

Funding can support EOM<sup>2</sup>, EQPT, OOE & Travel.

Apply via iGrants: <a href="https://app.a-star.edu.sg/igrants/">https://app.a-star.edu.sg/igrants/</a>.

See section on "Application Guidelines".

<sup>1</sup>Inclusive of overheads for non-A\*STAR institutes <sup>2</sup>PI EOM is not supported. At least 2/3 of FTE must be new staff/existing staff not in any funding

#### **IMPORTANT DATES** LOI **30**<sup>th</sup> submission **JULY** deadline 2021 2-day Biodesign 20th & 21st Workshop **SEPTEMBER** for BEP 2021 2021 for shortlisted applicants only Full Proposal 6<sup>th</sup> submission **OCTOBER** deadline 2021 for shortlisted applicants only

FARIY

**NOVEMBER 2021** 

Final Review

Presentation

for shortlisted

applicants only







### **ELIGIBILITY CRITERIA**

Teams must comprise at least:

- **1 Clinical PI**; with a primary appointment<sup>3</sup> in a public healthcare institution or academic medical school in Singapore and be salaried by the institution, and
- **1 Technical PI**; with >50% commitment in an A\*STAR entity.

Teams may choose to include multiple performers as **Co-Investigators** (Co-Is) on a single project, including performers from Institutes of Higher Learning (IHLs) and other public-funded research entities, but this is not mandatory.

All proposals must include **both technical and clinical deliverables** to demonstrate significant contributions from both the technical and clinical sides of each team.

<sup>&</sup>lt;sup>3</sup>Refers to medical practitioners registered in Singapore, including medical doctors, nurses, and Allied Health professionals, who have access to patients and can demonstrate that he/she can achieve the relevant clinical deliverables for the project, Deviations are subjected to approval.







### **REVIEW PROCESS & ASSESSMENT CRITERIA**

Under the BEP, submissions will be reviewed in 2 stages, as described below.

#### 1. LOI Review & Shortlist

From the LOI submissions received, **up to 12 teams** are expected to be shortlisted. LOIs will be reviewed by up to 3 LOI reviewers representing the technical, clinical and business domains.

2. <u>Final Review</u> (for shortlisted applicants only)

Teams are expected to present at the Final Review to a panel of reviewers from various backgrounds such as academic, clinical and industry. Final decision on funding will be decided after the Final Review.

### **Assessment Criteria:**

- 1. Technical feasibility
- 2. Clinical impact and feasibility for clinical adoption
- 3. Target market size and commercialisation potential







### **APPLICATION GUIDELINES**

Letter of Intent (LOI) shall be submitted electronically through iGrants.

E-mail applications will not be accepted. Incomplete submissions will be disqualified.

Applicants are advised to submit their applications early in the event of technical errors with the iGrants website.

If you encounter difficulties with account creation on iGrants, please write to <u>A-STAR\_OGA@hq.a-star.edu.sg</u> for help.

The following slides outline steps for "Using iGrants" and "LOI Submission".







### **APPLICATION GUIDELINES**

#### **Using iGrants**

#### 1. For first-time users:

- Under the landing page, click on the "Create New Account Link".
- Fill in the relevant information.
- Under Account Type, select "I will be submitting/supporting proposal".
- The "Primary Email" will be your login ID to iGrants. Please use official A\*STAR email address.
- Take note of the password requirements; password must contain 12-20 characters and at least:
  - 1 uppercase character
  - 1 lowercase character
  - 1 number
  - 1 special character
- Click "Submit" to register the account with iGrants.
- Upon successful registration, iGrants will send a notification e-mail to the primary e-mail address.

#### 2. For existing users:

- Log in using your existing username and password. If you've forgotten this, click on "Forget Password".
- If you are not able to login, this could be because your account has been locked due to inactivity. Please contact your Host Institute Admin to unlock your account.
- Click the "Login" button. On successful authentication, iGrants will display the Dashboard screen.







### **APPLICATION GUIDELINES**

#### **LOI Submission**

- To submit an LOI application on iGrants portal:
  - On the Dashboard page of the iGrants portal, under the Create tab, click "Proposal".
  - iGrants will display a list of Grant Calls that are currently open. From the list of Grant Calls, click on the "Apply" link for the "BEP Run 2 Call for Proposals".
  - A pop-up window should appear with a brief overview. Please only enter the required information into mandatory sections. For all other sections, it will suffice to attach the LOI Application Form (in pdf format).
  - Scroll down to access hyperlinks to download the "**LOI Template**" . Complete the form, and upload as an attachment.
  - Click on the "Submit" button to submit the LOI. Please note that once submitted, the application will go directly to the secretariat. This application will not be routed for endorsement through iGrants.
  - If any mandatory fields have not been filled, the system will reject the proposal and alert the user to errors and/or missing information. Once these errors have been rectified, the user should be able to submit the proposal.
  - Once a proposal has been submitted successfully, the system will return the Submitter to his/her dashboard.
- 2. For more detailed instructions on how to submit an application, please refer to the user guide 'iGrants Grant Application User Guide (External) Ver3.1" by clicking on the "User Guides" link on the iGrants landing page.
- Please direct iGrants-related queries to <u>A-STAR\_OGA@hq.a-star.edu.sg</u>







# TIMELINE OF EVENTS (INDICATIVE)

FOR ALL APPLICANTS & INTERESTED PARTIES				
Call for proposal	21 June 2021			
Virtual Roadshow for BEP; 2 sessions available	5 & 19 July 2021			
LOI submission deadline	30 July 2021			
Notification of LOI shortlisting outcome	Early September 2021			
FOR SHORTLISTED APPLICANTS ONLY				
Singapore Biodesign 2-day Workshop for BEP	20 & 21 September 2021			
Full proposal submission deadline	6 October 2021			
Presentation at Final Review	Early November 2021			
FOR SUCCESSFUL APPLICANTS				
In-principle approval	End November 2021			
Letter of Allocation	End December 2021			







## SINGAPORE BIODESIGN WORKSHOP FOR BEP

#### When is the workshop?

20 & 21 September 2021; 9 AM - 6 PM

#### Who should attend?

Only shortlisted teams after the LOI evaluation will be required to attend. Teams will be informed by **early Sep** if they have been shortlisted. **Up to 3 people per team may attend**. It is **compulsory for both the Clinical PI and Technical PI** to attend the 2-day workshop.

#### Why is this important?

The robust Biodesign methodology has consistently demonstrated an outstanding track record in the ability to **de-risk projects at the planning stages**, with a multi-disciplinary and systematic approach for the identification and validation of important unmet healthcare needs, the development of novel technologies to address them, and the subsequent development of business and commercialization plans to bring them into patient care.

Through this workshop, project teams can benefit from high-touch training support to inculcate a Biodesign approach in their projects, and gain a high-level understanding of the various processes and considerations in their journey towards market approval. This will help teams in drafting a full proposal that can address the evaluation criteria for the BEP.







## **CONTACT INFORMATION**

For general queries, please refer to the "BEP Run 2 FAQs v2.3".

If you require further clarification, you may reach us at <a href="https://example.com/HMT@hq.a-star.edu.sg">HMT@hq.a-star.edu.sg</a>. Please allow up to 3 working days for us to provide a response.

For queries related to iGrants, please reach out to <u>A-STAR\_OGA@hq.a-star.edu.sg</u>.

#### **HMT HTPO Seed Fund Secretariat**

Nigel Tan Douglas Goh Suhaila Binte Mohamad Zan Diana Wan









# **THANK YOU**

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# **Annex**









### **Description of TRL stages for Medical Device Development**

TDI	TDI Descriptions	Medical Device Readiness Level		
TRL	TRL Description+	Prototype Milestone	Software	
TRL 1	Fundamental Research	No prototype. Need finding, research, identification and brainstorming ideas		
TRL 2	Applied Research	*Breadboard/Experimental Prototype (BB)	Concept	
TRL 3	Research to prove feasibility	**Feasibility Prototype (PoC) + (Appearance Model)	Concept	
TRL 4	Laboratory Demonstration	***Working Prototype(WP)	Pre-Alpha	
TRL 5	Technology Development	Engineering/Alpha Prototype (EP)	Alpha	
TRL 6	Field demonstration of whole system	Verification/Beta Prototype (VP)	Beta	
TRL 7	Industrial Prototype	Manufacturing/Validation Prototype (MP)	Final stable release v1.0	

<sup>\*</sup>Commonly used by government funding agencies, investors, technology transfer office for measuring the status of a product getting ready for market/implementation.

<sup>\*</sup> Experimental prototypes are typically multiple individual assemblies of off-the-shelf parts, to investigate feasibility in an exploratory study.

<sup>\*\*</sup> Feasibility prototypes are assemblies which have the core functions plus any new, unique or difficult functions to demonstrate feasibility and investigate risks. It may not look like the end-product.

<sup>\*\*\*</sup> Working prototypes are typically works-like models with most of the intended functions/ features. It is used for internal development to uncover integration issues, refine requirements and selection of key components.