

IHealthE Innovation Catalyst Awards

Guidance document

Contents

Overview of the Innovation Catalyst Awards

Terms and Conditions

Expression of Interest Form Guidance

FAQs

Overview of the Innovation Catalyst Awards

The Tyree Institute of Health Engineering (IHealthE) has established the Innovation Catalyst Awards to provide tailored support to the progression of promising medical technology and software innovations through the translational pathway towards implementation in the clinic. These awards form a core part of our vision to be a global leader in transforming healthcare practice and delivery by translating innovative, transformational, and cost-effective health and medical technologies to meet patient and clinician needs.

Awardees will be provided with up to \$50k of personalised translation support over a twelve-month period to address key barriers to progress. The targeted areas of support include:

- Building a world class team
- Developing a prototype to prove a solutions concept
- Creating a compelling business plan
- Developing a regulatory strategy or IP strategy
- Obtaining clinical validation

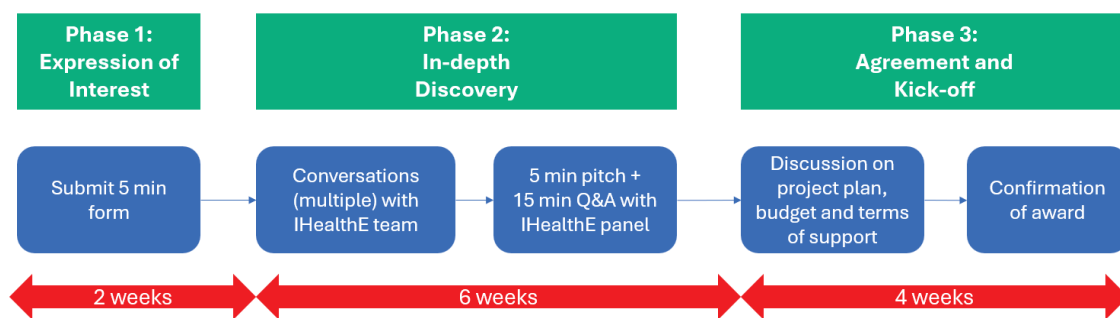
The end goal of the Health Tech innovation journey is the innovative solution becoming the standard of care. For this to happen the solution needs to provide clinical value in a financially sustainable way for the healthcare system and the company making it.

To help Health Tech innovators to structure key steps and requirements of the innovation journey, the IHealthE team leverages the [Healthcare Innovation Cycle](#), a framework developed by the Consortia for Improving Medicine with Innovation & Technology. The framework breaks the innovation journey down into activities and milestones that build on each other across four key domains: Clinical, Business, Regulatory, Technology. The activities you perform reduce the risks that stop progression and build evidence to convince you (project team) to continue the journey, funders (gov. grants, angels, VCs) to put money towards the project, and ultimately

stakeholders (users, choosers, payers) that you are developing something of value to them.

At this early stage of the Health Tech innovation journey there are many unknowable unknowns, and while each project is different, and there is no guarantee of success, being supported by an experienced team is extremely valuable. IHealthE’s Catalyst Award will be used to support activities that address key barriers to your projects progress. In addition, IHealthE’s Professors of Practice with years of experience can provide guidance to activities, such as: deal making/structuring to ensure maximum value is retained within the start-up, creating research protocols that allow results to also be used in regulatory submissions or as evidence of value to payers, compiling the necessary set of materials that investors would require as part of their due diligence, and much more.

Selection process



The Innovation Catalyst Award selection process has three phases:

- **Phase 1:** Fill out an expression of interest form that takes less than 5 minutes to complete. You will provide details of the unmet need and its impact and, if you have one, a solution and the work you have done to develop it.
- **Phase 2:** Shortlisted applications will be engaged by our innovation team to better understand the key aspects of the proposed innovation and crystallise the key translational challenges. This will culminate in a 20-minute presentation with Q&A to a panel of experts for final selection.
- **Phase 3:** Up to 6 successful applications from Phase 2 will enter discussions to finalise the scope of IHealthE support and sign an agreement before the support commences.

Applications will be assessed on a rolling basis and may be selected for progression in advance of the closing date to facilitate expedited project kick-off. Successful applications will detail key aspects of successful innovation, including the significance of the unmet need, the translational ability of the technology, and the feasibility of a

sustainable business model. Additionally, they will clearly articulate the reasons for the chosen support and a plan of activities for the 12-month award timeline.

We want to see you succeed and believe our facilitation and support offering through the Innovation Catalyst Awards will be a key ingredient in helping you achieve success.

Apply here: <https://www.ihealththe.unsw.edu.au/catalyst-awards>

If you are unsure you fit into the innovation catalyst awards or would like to discuss before applying, please contact us at ihealththe@unsw.edu.au

Terms and Conditions

1. Eligibility:

- a) The Innovation Catalyst Awards program is open to any healthcare innovator with a clinical, technology or business background, looking to develop innovative solutions to healthcare challenges.
- b) The proposed innovations to be developed under this program must be a medical device or software solution (we do not currently have the capacity to support other types of solutions e.g. pharmaceuticals, process innovation).
- c) If not already part of a team, the innovator must be open to accepting suitably qualified team members.

2. Expectations:

Expectations and responsibilities of Awardees if funded:

- a) Awardees agree to becoming members of IHealthE as part of accepting the award. Members are required to include IHealthE as an affiliation for the purpose of any publications. Details of IHealthE membership benefits can be found here: <https://www.ihealthe.unsw.edu.au/membership>
- b) Support for projects under the Innovation Catalyst Award will continue for up to 12 months or until \$50k in support is utilised (whichever comes first).
- c) We are looking to support innovators who value ongoing translation support though the journey of bringing innovations to the clinical.
- d) Funding disbursement: IHealthE will procure and pay agreed service providers (both internal and external) up to the amounts agreed on acceptance of award.
- e) A binding Agreement between the Awardee and IHealthE will be signed by all team members prior to receipt of support. The Agreement will include these Terms and Conditions, the agreed scope of IHealthE support, project milestones, outcomes, and budget.
- f) Awardees must nominate a project leader who will be responsible for timely communication and reporting of project progress to IHealthE. IHealthE will assign a Program Manager responsible for supporting Awardees in achieving consistent progress towards agreed milestones.
- g) Tracking of expenditures will be conducted by IHealthE Program Manager in a transparent manner with the Project Leader. Any unanticipated variation in schedule or expenditure must be agreed by the IHealthE Program Manager.
- h) The Awardee key point of contact / project leader will be required to commit to a minimum of 2 hours of progress review and facilitation discussions on a fortnightly basis.

- i) The IHealthE Program Manager will report on Awardee progress on a Quarterly basis. Projects without sufficient progress will be flagged for review by IHealthE management. IHealthE reserves the right to terminate support for Awardees that do not demonstrate sufficient progress or commitment as determined by the IHealthE management review.
- j) From time to time, Awardees will be requested to present at IHealthE events, including a showcase, morning teas, Awardees commit to participating in these events where their schedule permits.
- k) Awardees agree to include an acknowledgement to IHealthE, UNSW, and the Innovation Catalyst Awards in any related public presentations and publications.
- l) Awardees consent to having non-Confidential Information regarding the project and outcomes shared publicly for IHealthE marketing purposes.
- m) For IHealthE facilitation and support beyond the agreed scope and duration of the Award, Awardees are requested to include a budget for 'translation and commercialisation facilitation' services to offset IHealthE costs in any future requests for funding to external parties.

3. Confidentiality, intellectual property and publication policy:

- a) Confidentiality obligations: Both parties must and must ensure to keep secure and maintain the confidentiality of any Confidential Information of the other party and refrain from using or directly or indirectly disclosing any Confidential Information of the other party, or attempting to do so, except to the extent necessary to perform the agreed activities of the project.
- b) Publications:
 - i. Each party is entitled to publish the results of the Project provided that no Confidential Information owned by a non-publishing party is disclosed.
 - ii. Acting reasonably, each non-publishing party may, within a thirty (30) day period do any one or more of the following:
 - provide comments on the proposed Publication to the publishing party, which that party must consider but is not obliged to follow;
 - require the publishing party to delay Publication for no more than ninety (90) days to allow the non-publishing party to file patent applications or take other measure to protect its proprietary rights; and/or
 - require the publishing party to remove specified Confidential Information from the Publication.

c) Intellectual Property:

- i. IHealthE will not assert IP rights as part of the Innovation Catalyst Awards program, however, joint work with collaborative parties (e.g. UNSW researchers, other clinicians) that could result in co-creation of intellectual property has to be assessed and agreed to by the respective Awardees. Emergent IP will be monitored by the Program Manager of IHealthE with a view to IP protection if and when necessary. We are committed to fair and equitable management of IP. Equitable management of IP will depend on a range of factors including the maturity of the solution being developed, sources of funding, employment relationships and inventive contribution. We aim to provide clear and personalised advice on guidelines and best practices to ensure appropriate pathways for effective protection of IP based on the circumstances.
- ii. All project team members need to declare if they are bringing any background IP to the project

Expression of Interest Form Guidance

This document provides guidance on the key points to address for each question on the Expression of Interest form, to articulate the nature of the unmet need and steps (if any) you have taken to address this need. [Link to online form](#)

Question 1: Full name

Question 2: E-mail address

Question 3: Phone number

Question 4: What is your area of clinical practice or medicine & health expertise?

Please indicate areas of medicine and health to which your experience and expertise most aligns. E.g. Cancer biology, digital health, healthcare procurement, etc.

Question 5: Please list all employment affiliations:

- Please indicate institutions at which you work or are affiliated to.

Question 6: Please list all healthcare professionals that are involved in the project (names and roles):

- Please indicate clinicians who have/are contributing to the project, their expertise relevant to the project, and what role they play in the project.

Question 7: What is the healthcare problem?

- Describe the clinical scenario and articulate why there is a need for a better solution. Focus on the key issue or root problem without mentioning your solution. You can identify limitations in current clinical tools.
- e.g. During labour, the heart rate monitor sensing the baby's heart rate incorrectly picks up the mother's heart rate. This occurs approximately once an hour. There is a need to measure foetal heart rate more accurately and consistently, ideally non-invasively.

Question 8: Who does this problem impact?

- Detail things like patient cohort, hospital staff involved, the incidence rate, how often an activity is performed, how many clinicians are affected, how great is the pain point – is there mild frustration at existing devices or genuine lack of options. Provide objective data on the current clinical and/or cost impact to the health system (e.g. cost savings, time savings, readmission rate, length of stay in hospital, QALY, etc.).

- e.g. In the US, approximately 250k C-sections are performed due to non-reassuring foetal heart rate traces (~25% of C-sections). This has the largest impact on patients and insurance companies due to the trauma and costs (\$35k each) of the C-section. On a day-to-day basis, it would reduce the burden on nursing staff and doctors due to false alarms.

Question 9: What is the desired outcome from a solution to this problem?

- Think of who is most motivated to have the problem solved, what outcome metric would they judge a solution, and what improvements in the outcome metrics mentioned in Q6 are desired for a solution to be successful.
- e.g. Decrease the number of unplanned C-sections due to non-reassuring foetal heart rate traces by 40%. This would save patients and insurance companies \$20k per birth, totalling \$2m per year. It would also reduce patient and family anxiety levels, and frustration levels of hospital staff due to false alarms.

Question 10: Do you have a solution to the unmet need in mind? (Yes / No)

There is no expectation to have a solution, if you have one in mind the following questions will give us more information on the work you have. If you answer yes to Question 9, answer the following questions in one or two sentences.

Question 11: What stage is your proposed solution?

Select from the following:

- Idea
- Drawing or list of features
- Prototyping
- Product ready for clinical trials

Question 12: Describe your solution in one sentence.

- e.g. A wishbone shaped clip that attaches to the mitral valve to help it close more completely.

Question 13: Have you approached others with capabilities to develop a solution?

Select those that apply:

- No, I haven't yet
- Researchers
- Product designers
- IP Lawyers
- Regulatory specialists
- Start-ups advisers
- Other (please describe)

Question 14: How much funding has gone into the project (e.g. personal finance, grants, or accelerators)?

Select from the following:

- \$0
- \$1 – \$5,000
- \$5,001 – \$20,000
- \$20,001 – \$50,000
- Over \$50,000

Question 15: Have you attempted to understand the regulatory pathway for your solution to be approved for use in the clinic?

Select those that apply:

- No, I haven't yet
- Yes, I know the device classification
- Yes, I know the applicable regulatory pathway
- Yes, I have regulatory strategy

Question 16: Have you thought or discussed with others about how this solution is incorporated into the clinical workflow?

- e.g. The device will be used pre-operatively by nursing staff, I have received positive feedback when discussing with colleagues in Australia and overseas at conferences.

Question 17: Do you have a clear idea how this solution will be sold into the healthcare system, who would purchase and who would pay for it?

- e.g. It would be the same as current products we use, which are procured on a tender every 3 years. This is managed by the local health district.

Question 18: What were the barriers (if any) preventing you from pursuing the development of this innovation earlier?

FAQs

Who can apply for the Tyree IHealthE 2024 Catalyst Awards?

Any individual or team who is trying to find or is developing a solution to a healthcare unmet need should apply. Applicants must be able to demonstrate they have detailed knowledge of the relevant clinical environment and its key stakeholders.

What are the key dates?

Phase 1 applications will close on 30th August 2024. Phase 2 will be completed in September. Awardees will be chosen, and agreement signed for Phase 3 to start in October 2024.

What types of innovations are eligible?

Our expertise and capabilities are in medical devices and software-based solutions. We currently don't have capacity to support drugs, biologics, or process improvements.

I already work with a team, can they be involved?

A team is not a requirement for applications. Having the right people on the team at the various stages of the healthcare innovation journey is crucial to success. So if you already have them, that's a bonus.

Is this research funding?

No, this award does not support basic research. The award is to support early-stage translation activities.

What support is provided?

Support is focussed on the key activities in the [Healthcare Innovation Cycle framework](#) (developed by CIMIT) each project needs to progress. Conversations between applicants and IHealthE during Phase 2 will include agreeing on what boxes have been ticked and what boxes are the most important to tick next, and which of these activities IHealthE can support or facilitate. Broadly, support is provided across the following areas: building a world class team, developing a prototype to prove a solutions concept, creating a compelling business plan, developing a regulatory or IP strategy, and obtaining clinical validation.

If this is not research funding, how will funding be utilised for translation activities?

We will come to an upfront agreement of how the award budget will be utilised (e.g. engineering and materials for developing a prototype, personalised commercialisation workshop and monthly sessions with IHealthE Professors of Practice) and track utilisation of the budget.

How will the funding be disbursed?

This is not a cash award. IHealthE will procure and pay for service providers (both internal and external to IHealthE) up to the amounts agreed on acceptance of award.

What criteria will be used to evaluate the applications?

Phase 1 applications will be evaluated based on the clarity and depth of information provided. Details on the evaluation for Phase 2 will be provided to shortlisted applicants.

Can I submit more than one unmet need?

Yes, but remember we want you to be committed to the project so your best application will likely be an unmet need you have been thinking about for a while.

Will IHealthE take equity as part of its support in the Innovation Catalyst Awards?

IHealthE will not take equity as part of its support.

Is the application process confidential?

All information provided will be treated commercial in confidence. The review panel will be held to strict conflict of interest disclosure. We don't expect you to provide confidential information during the application process. Confidentiality agreements can be signed by both parties if requested.

What does the team point of contact/project leader do?

This person will be responsible for correspondence between the project team and IHealthE. They will be required to commit to a minimum of 2 hours progress review and facilitation discussions on a fortnightly basis. They will work closely with the IHealthE project manager to track expenditures and progress towards milestones.

What does the IHealthE Program Manager do?

This person will be responsible for correspondence between IHealthE and the project team. They will work closely with the project leader to track expenditures and progress towards milestones, and report to IHealthE executive team on the progress of the project.

How will IP be handled?

IHealthE will not assert IP rights as part of the Innovation Catalyst Awards program, however, joint work with collaborative parties (e.g. UNSW researchers, other clinicians) that could result in co-creation of intellectual property has to be assessed and agreed to by the respective Awardees. Emergent IP will be monitored by the Program Manager of IHealthE with a view to IP protection if and when necessary. We are committed to fair and equitable management of IP. Equitable management of IP will depend on a range of factors including the maturity of the

solution being developed, sources of funding, employment relationships and inventive contribution. We aim to provide clear and personalised advice on guidelines and best practices to ensure appropriate pathways for effective protection of IP based on the circumstances.