

## EPSRC Place Based Impact Acceleration Account

### Innovating Medical Technologies Across the Yorkshire Region

#### Impact Projects Guidance Notes

##### 1. Background

The Place Based Impact Acceleration Account (PBIAA) is an EPSRC scheme providing four years of funding to support a programme of impact activities within a research and innovation cluster. This PBIAA is based on the medical technologies (MedTech) cluster in the Yorkshire region and will support the translation of university research into new clinical products and services. It is one of ten PBIAAs awarded in the first round of the scheme and is led by the Universities of Leeds and Sheffield ('the consortium'). The funding will support projects that accelerate impact from university research.

Three types of impact funding are available through the PBIAA:

- Due diligence/Proof of market projects (up to £10k)
- Proof of feasibility projects (up to £20k)
- Proof of concept projects (up to £100k)

The projects will be allocated following an application and peer review process. This document describes the scope of the funding, the different types of project available and how to apply.

##### 2. Aims of the Impact Project funding

The aim of the funding is to support the progression of medical technologies arising from university research along the translation pipeline and facilitate the early stages of their commercialisation.

##### 3. Application Guidelines

###### Scope:

- All impact funding must be for projects relating to medical technologies. Medical technologies are defined as devices, tools and machines used for the diagnosis, prevention, monitoring, treatment or alleviation of disease, injury, or disability. The scope does not extend to biopharmaceuticals, or technologies used only for wellbeing/fitness.
- Projects should be at least 50% within the EPSRC's remit but need not link to prior EPSRC funding.
- Projects must support and contribute to the growth of the Yorkshire region MedTech economy.
- Projects must be led by a member of academic staff at a UK higher education institution.
- *For the first call only: the lead applicant must be a member of academic staff at the University of Leeds or Sheffield. All future calls will be open nationally.*

#### Ineligible activities/costs:

- × New, fundamental research.
- × Top-up funding for pre-existing projects.
- × Non-Specific Public Engagement activities and science communication. However, funding may support targeted user or patient engagement to identify user requirements.
- × Any costs relating to intellectual property protection including but not limited to registering, maintaining, or supporting patents or property rights
- × Undergraduate or postgraduate activities/training; core PhD training including tuition or bench fees.

#### 4. Types of Impact Project Funding

Three different types of Impact Project are available:

- **Due diligence/Proof of market projects (up to £10k):** Small initial pieces of work to establish a market or clinical need, including market research, competitor technology analysis, IP reviews, regulatory strategy, studies to obtain external commercial, clinical or patient opinions. Outcomes from these studies should establish the market and clinical need, and provide a plan to progress the technology or concept towards commercialisation.
- **Proof of feasibility projects (up to £20k):** Activities to demonstrate the feasibility of a technology concept, initial prototype development and testing, and ensuring a technology is designed to meet user demands from the outset. Where needed to identify user requirements, engagement with diverse patient groups, representative of the whole target population, will be promoted.
- **Proof of concept projects (up to £100k):** Larger technical development programmes to achieve commercially identified milestones. Typically 12-18 months in duration, co-developed with end users to demonstrate technical and commercial feasibility. Only projects that have proved the technical feasibility and market need (either through PBIAA funding or other means) are eligible for proof of concept funding. To ensure relevance, projects must have a co-investigator from an appropriate clinical specialty and a commercial partner (either an industrial partner or, where a case can be made that this is not appropriate, then a commercialisation support organisation). The partner should provide financial or in-kind support commensurate with the commercial opportunity. Stop-go points must be identified at the outset to allow fast failure in higher risk projects. Outcomes should include evidence (e.g. preclinical evaluations of a technical prototype) to provide greater confidence for commercial investment. These projects must identify a well thought out R&D/ product development plan and a clear proposed business model for future exploitation of the technology.

#### 5. Calls and evaluation processes

Calls for impact funding will take place every six months and will be advertised internally within the consortium universities as well as regionally and nationally through our networks, supported by our Advisory Board. A panel will be convened for each call with an independent chair. Each application

will be scored by members of the panel against a set of criteria and the panel will then form a ranked list, with recommendations to fund or decline funding based on the criteria. If necessary, the panel can request further clarification from the applicant prior to making a decision.

The deadlines for forthcoming calls are below. Award notifications will be sent two/three weeks after the call deadlines:

- Wednesday 26<sup>th</sup> June 2024 (Principal Investigator from Universities of Leeds or Sheffield)
- *November 2024 (date tbc)* (Principal Investigator from any UK HEI)

To apply, use the relevant application form available via the PBIAA website. Please email a signed electronic copy of the completed application form to [PBIAA@leeds.ac.uk](mailto:PBIAA@leeds.ac.uk).

## 6. Applicant Eligibility

- Investigators, including the Principal Investigator (PI) may be any researcher who at the point of application holds a current contract of employment at a UK higher education institute which will last the duration of the proposed activity for which funding is applied for.
- All applications must be approved and signed off by the PI's Head of School/Department to ensure that the applicant is able to apply for funding in line with their employment contract.
- Applications led by, or with a significant proportion of team members drawn from, early career researcher communities (including post-doctoral researchers and researchers on fixed funding/ term contracts) are welcomed. However, at least one member of the applicant team must have an academic contract at lecturer level or above; they would normally be expected to be the originator of any related IP.

## 7. Costs

Applicants should provide a project costing with their proposal that must be prepared in conjunction with the relevant research finance office at their university. Successful projects will have an account set up for these costs.

Awards will only cover the direct costs associated with the project. VAT must be included in the figures as the University cannot reclaim VAT from this project.

Investigator costs are ineligible for funding except where an Investigator meets the applicant eligibility requirements and is employed on a fixed funding/term contract: in this case, their Investigator DI costs may be funded if this is not part of an external collaborator cash contribution.

You should provide full financial details of the project, including salary costs, travel and subsistence costs, additional consumables and any other fees associated with the project.

Funds can be used to support existing staff employed by the University or to recruit new members of staff if necessary to meet the skill requirements of the role, providing this can be achieved in an appropriate timescale for the implementation of the project. Projects can be carried out on a full-time or part-time basis, depending on the nature of the work. Projects may involve one or more researchers. The award could also be used as leverage for, or form part of, a longer-term project, in

which case the external partner would be expected to fund any work beyond the initial funding period.

Applicants for Proof of Concept funding should include costs for project management and commercialisation support (see Project Management and Commercialisation Support), which can be through specialist external organisations. Applicants for Due diligence, Proof of Market and Proof of Feasibility can request costs for external organisations to provide specialist services to gain market intelligence, develop a commercialisation plan, or understand user needs, regulatory pathways, IP landscape etc.

The following costs are not eligible to be funded through the PBIAA (but could be funded by the external collaborator or internal fund if appropriate):

- × Academic supervision (Investigator DI or Investigator DA – see previous exceptions)
- × Items of equipment with an individual value of £10,000 or more (items of equipment over £500 must be detailed in the justification of resources)
- × Laptops, i-pads etc. unless robust justification is provided
- × Undergraduate or masters level activities, or core PhD costs including stipend, training, tuition or bench fees
- × Any costs relating to Intellectual Property protection including but not limited to registering, maintaining, or supporting patents or property rights.
- × Indirect costs, estates, or infrastructure

Costs associated with attendance at workshops / conferences will be considered but must be detailed in the justification of resources section of the application.

## 8. Assessment criteria: Proof of Concept projects

### *Filter (Y/N) questions*

- Projects must be within the scope of this PBIAA (see Application Guidelines)
- The basic underpinning research should have already been funded and completed with demonstrable outputs. The technology should be ready for POC funding and the proposal should enable proof of concept to be defined.
- The commercial opportunity and clinical need must have been established previously (through PBIAA funding or other sources), and there should be both a clinical/healthcare partner and an industry/commercialisation support partner involved in the application.

### *Quality of the Proposal*

- The proposal is novel and translational addressing a clear clinical/market need.
- The scientific and technical information is clear, appropriate and robust.
- The objectives and plan of work are appropriate and realistic.
- The outputs and deliverables meet the aims of the project and are achievable in the time and funding requested.
- There is an appropriate evaluation of risks in relation to the project timescales and team.

### ***Ability to Deliver***

- The project team has the skills required to deliver the work described with appropriate collaborations in place.

### ***Clinical Need/potential for patient benefit***

- The proposal has the potential to address a significant clinical need with a clear benefit for the patient and/or healthcare provider
- There is an understanding of the affected/treatable patient populations

### ***Commercial Opportunity/IP***

- The proposal should demonstrate a genuine commercial opportunity with evidence of the market potential.
- The proposal must clearly demonstrate and explain its potential to support growth of the Yorkshire regional MedTech economy.
- There is evidence of industry need and commitment through a relevant partner. For applications with an industry partner, then the partner should be providing cash or in-kind support commensurate to the commercial opportunity. If there is no industry partner, then the case should be made as to why this is not appropriate (for example, if a spin-out approach is proposed) and there must be evidence of partnership with other organisations to provide adequate commercialisation support.
- All university and/or external collaborator(s') Background IP associated with the project are summarised.
- Plans for protecting and exploiting foreground IP should be clearly defined and plans for sharing benefits take into account the ratio of cash and/or in kind contributions of external partners with the University/UKRI contributions. **Note:** As this is a collaborative partnership, rather than contract research, both the University and External Collaborator(s) should share the benefits, e.g. consider a creator owns results model, or perhaps ownership of results by field of interest if appropriate, or other similar equitable option.

### ***Realistic follow-on plan***

- The proposal should demonstrate a defined and realistic pathway to market
- The follow-on plan is clear and well thought through
- The key stakeholders required for successful commercialisation are clearly defined and, where not already part of the bid, there are appropriate plans for engagement.

## **9. Assessment Criteria: Due Diligence and Proof of Feasibility projects**

For the Due Diligence/Proof of Market and Proof of Feasibility projects, a subset of the above criteria will be used:

### ***Filter (Y/N) questions***

- Projects must be within the scope of this PBIAA (see Application Guidelines)

- The basic underpinning research should have already been funded and completed with demonstrable outputs.

### ***Quality of the Proposal***

- The proposal is novel
- The scientific and technical information is clear, appropriate and robust.
- The objectives and plan of work are appropriate and realistic.
- The outputs and deliverables meet the aims of the project and are achievable in the time and funding requested.

### ***Ability to Deliver***

- The project team has the skills required to deliver the work described with appropriate collaborations in place.

### ***Clinical and Commercial Need***

- There must be some evidence of clinical or industrial need, but this may be based on preliminary discussions or available literature.
- For patient/user engagement studies, there must be consideration for the diversity of the target users/patient population the how this will be accounted for in the proposed activities.
- Projects should consider the likely impact on reducing health inequalities across the region.
- For proof of feasibility studies, there should be some preliminary description of the device/technology, its intended purpose and labelling, and likely users, although the funding can be used to provide evidence to refine these.

### ***Follow-on Plan***

- There should be some explanation of the likely next steps, and justification of how the project will provide evidence needed to progress, however development of more detailed follow-on commercialisation plans may be part of the project.

## **10. Partner Letters of Support**

Eligible project partners can be from clinical, industrial, civic, standard agencies trade bodies, charities and research trade organisations. These letters should be on company headed paper, signed and dated within six months of the proposal submission date. The letters will provide a background to the project partners expertise and why they are interested in supporting this project. Letters should also highlight the commercial and/or patient value proposition of the development/product.

For example:

- What existing products or procedures would this technology replace?
- Where do you feel the real market opportunity lies for this technology?
- How would this technology fit with your current technology portfolio?
- How would this technology impact on your commercial competitiveness?

The partner letters may also cover how they are supporting the product development roadmap. For example, they may cover how they are assisting to bring this device/technology to market and the estimated timescales. These activities could include supporting:

- Regulatory compliance activities
- Pre-clinical and clinical trials
- Manufacturing scale up activities including sterility assurance
- Opportunities for further collaborative projects

All partner contributions should be quantified including:

- In-kind support (materials, facilities, processing, scientist/ technicians support)
- Time to attend meetings and review research/ project outcomes
- Financial support to the project
- Advice/technical/commercial/IP guidance

## 11. Project Management and Commercialisation Support

Proof of Concept projects must have a designated Project Manager who can provide specialist MedTech innovation and translation support. In most cases, this support will be through an external organisation providing specialist services, such as PBIAA Project Partners Medipex ([www.medipex.co.uk](http://www.medipex.co.uk)) or Medilink ([medilink.co.uk](http://medilink.co.uk)), although internal support within the University through a research or technology transfer officer may be appropriate in some cases. Please contact the PBIAA team if you require support in finding an appropriate partner. For Proof of Market and Proof of Feasibility projects, external support or commissioned pieces of work may be necessary. In all cases, external consultancy/support can be included in the costing.

For Proof of Concept projects, matters relating to IP should be discussed with your university Commercialisation or Technology Transfer Office. A member of the office is required to review and sign the proposal.

## 12. Funding Conditions

All successful Impact Project applicants agree to submit a report on completion of the project (as described in [Reporting Requirements](#)) and will be expected to participate in future capacity building events and public engagement activities to share their experience and develop expertise.

For Proof of Concept funding only: successful applicants will be expected to provide a report every quarter that is reviewed and commented on by their designated project manager. The funding may be stopped, or a revised plan may be required, if the requirements to pass a stop/go point are not met.

An appropriate collaboration agreement must be in place between collaborating partners. External collaborators must have been vetted by the University of Leeds through a Risk Review Process before the project commences and funding is released.

For projects requiring the deployment of a researcher during the lifetime of a pre-existing grant, the consequence of any delays to the delivery of that grant should be managed and mitigated against before the project starts. Any extension to the pre-existing grant must be discussed and agreed with

the funder before the PBIAA-funded project takes place. It is the responsibility of the Principal Investigator to liaise with the funder of any pre-existing grant regarding any extension arrangements.

Except for salary, equipment, and conference costs, the transfer of funds between budget headings is permitted without prior permission provided that funds will only be used to meet the cost of activities that meet the agreed aims and objectives of the project.

If a no cost extension is required, a request should be made to the PBIAA Portfolio team, [pbiaa@leeds.ac.uk](mailto:pbiaa@leeds.ac.uk), accompanied by appropriate justification. Requests for extensions beyond the end of the PBIAA funding period (31<sup>st</sup> January 2028) will not be permitted.

Successful applicants must inform the PBIAA Portfolio team [pbiaa@leeds.ac.uk](mailto:pbiaa@leeds.ac.uk) if they are awarded funding from other schemes to support the same or similar activities.

### 13. Reporting Requirements

Report templates will be provided to successful applicants, comprising a quarterly report (for Proof of Concept funding only), a completion report and a rolling record annually thereafter.

The reports required for these projects are:

- **A Quarterly Report** for Proof of Concept projects will be required to be submitted at the end of each quarter. The report should provide brief summary of work completed against each of the milestones and status tracking using red-amber-green indicators. Where a stop/go point has not been successfully passed, there will be a requirement to meet with the project manager and members of the PBIAA executive to agree if the work should be revised or stopped.
- **A Completion Report** for all projects will be required to be submitted within 2 months of the project completion date, outlining how the objectives of the project and the relevant KPIs have been met, and future plans.
- **Annual Reports** will be required for three years following completion, tracking how the objectives of the project and KPIs are progressing alongside any new or unexpected developments since completion.
- Applicants will also be required to support the annual tracking of outcomes and impacts from PBIAA-funded activities through **Researchfish**<sup>®</sup>.

For information the outputs, outcomes, and impact measures that UKRI ask us to report on are detailed in Appendix 2. By accepting the award, the applicants agree to engage with the Innovation and Business Development team to monitor project progress both during the life of the project and post project to allow the reporting of outcomes and capture of impact. This will include making non-confidential aspects available to assist with the development of case studies.



## Appendix 1: Definitions

*Background IP* means any data, database/ materials (human or otherwise), inventions or general Know-how needed in order to carry out the project but created before or outside the scope of the project.

*Foreground IP* means intellectual property which will be created during and in connection with the project, for example all results, reports, materials, inventions whether patentable or not, data, or samples, prototypes etc. (i.e. the project outcomes).

*Know-how* means Information, skill or expertise, including processes, methods, techniques, (e.g. the most efficient means to synthesise a material) drawings, data or a compilation that is generally confidential and separate from proprietary intellectual property rights such as copyright, registered patents or design rights).

## Appendix 2: Key Performance indicators for the PBIAA Award and targets set out in the proposal

<b>Activities</b>	
Translational projects	135 projects (40 proof of concept, 45 proof of feasibility, 50 proof of market/due diligence of which: all with clinical partner, 50 with industrial partner (40 with SMEs); 25 with >1 academic group; 30 with non-consortia HEIs
Events and training	12 events (annual showcase and co-delivered workshops), and 16 training activities to facilitate knowledge exchange and impact
Secondments	20 outward or inward secondments to support knowledge exchange
Public/patient	30 discrete PPIEP activities of which 20 targeted at patients
Collaborations	50 new collaborations (academic-academic, academic-industry, academic-clinical)
<b>Additional funding</b>	
Contributions to PBIAA	Total support from industry (£500k cash, £500k in kind), HEIs (£900k staff), civic partners [combined authorities and NHS organisations] (£400k staff)
Follow-on	£10m further public sector support secured
<b>Outputs outcomes and impact</b>	
During PBIAA	200 publications, 30 new prototypes or pilots developed; 15 products advanced to higher TRLs through licencing or spinout companies.
Follow-on	£10m of secured downstream private sector investment
By 2035	By 2035 this will result in 10 new MedTech products or services on the market (additional £200m revenue) that go on to benefit 2m patients
<b>People trained</b>	
	600 people trained through PBIAA-supported knowledge exchange and training events; 200 staff actively involved in the delivery of PBIAA supported activities including 100 early career researchers.
<b>Partnerships and support</b>	
Support	200 research concepts supported through advice from the PBIAA team, including facilitation of 50 face-to-face discussions with companies and investors
Partnerships	30 new partners participating in collaborative proposals leading to 20 continuing after initial PBIAA supported activity and £1m of additional commercial investment in HEIs (e.g. through studentships or facilities)