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Confidence 4 Translation

Confidence For Translation

Information Workshop

18th June 2024

CONTACT US

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translation@manchester.ac.uk

@Translation_Mcr

MANCHESTER 1824

The University of Manchester

wellcome

AGENDA

10:00-10:20

Translation Manchester Accelerator Awards and C4T information session

Sam Butterworth, Elli Marinopoulou, Alessandro Faroni

- *Awards Intro and Timelines (EM)*
- *Top Tips: Dos and don’ts (SB)*
- *New Costing Process (EM)*

10:20-11:00

Questions and answers

- *Including eligibility questions and brief guidance on specific questions on the C4T application form if required*
- *Recording and slides will become available*

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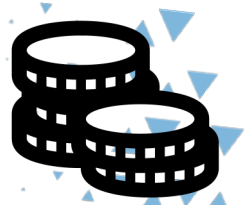
Call now OPEN



- Overcome a specific bottleneck that is preventing progression along the translational pathway, to address an unmet clinical need or improve an aspect of healthcare delivery, e.g.:
  - Prototype manufacturing
  - Proof of concept
  - Patient centred research
  - Collaborating with industry
- Not intended to fund an entire project, designed to overcome a bottleneck, applications from all stages are welcomed
- Maximum **£75k** for projects 6-9 months in duration
- Applications with Access To Expertise (A2E) remit are also accepted
- Salary (not the PI's), service, and consumable costs

Supported by: UKRI Medical Research Council
Impact Accelerator Account 2022-26

With contributions from: wellcome NIHR | Manchester Biomedical Research Centre

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Key dates

w/c 24th May

Call opens

Today

WE ARE HERE

Workshops

Information Workshops (12th and 18th June)

Costing workshops 25th June

10th July

Application Deadline

Peer Review Begins

Sept

Funding Panels

Notification of outcomes: w/c 7th October 2024

Nov

Projects Start

Projects start end of October onwards

Direct all enquiries to translation@manchester.ac.uk

Top tips

DOs

DON'Ts

Top tips: The Unmet need

Clearly articulate unmet need and the USP of your solution;

A good understanding of the current/emerging landscape is critical

You don’t have space to sell two ideas... Focus on the most promising application of your approach

Top tips: Key hurdles

Make sure you identify key hurdles;

What are the most awkward questions you have been/could be asked?

Consider line of sight to patients/utilisation – both clinical and regulatory input will ultimately be needed

If the proposal doesn't address risk, it may not be suitable for UKRI IAA full project funding

Top tips

- It may help to think about further funding options – and also to include any feedback you have from downstream funders.
- Make sure you have freedom to exploit your innovation... If licences to third party technology, you need to demonstrate these are in place/achievable
- Write the application for specialised audience in your research field as the panel will have generic , broader scientific / translational expertise
- Avoid catchy headline figures unless substantiated by data and analyses

Strong proposals will show:

- Specific bottleneck to be addressed with funding
- Demonstrable shift in the translational pathway
- Clear and specific objectives with associated milestones
- Clear translational vision (short and long term)
- Clear plan for follow on funding
- Clarity on IP situation
- Key personnel and experts identified
- All licences and ethical approvals in place or with clear/feasible plan

Common mistakes

- Lack of translational focus
- Insufficient technical details – all our external panels and reviewers are under CDA
- Key expertise lacking from the team
- Study design and sample sizes not fully justified
- Doubts about plan or its execution / cost or time not justified
- Milestones not measurable and poorly aligned
- Insufficient consideration of competition or differentiation from existing approaches

Summary: Key aims of proposals

- What is the underpinning problem or need?
- Where are you now, and what is the bottleneck you are experiencing?
- What, specifically, will this project achieve?
- What are the alternatives solutions and why is this better?
- What are the risks to the project and how will these be managed?
- What is the long-term translational plan?

Costing the application

- Costing of internal funding applications now need to be calculated **by the applicants** using the **BlackDackel Research Costing tool** – Do not contact Research Services.

- Information on how to use **BlackDackel** can be found on the application brief and FAQs document.

- A **dedicated costing workshop** for C4T applications will take place on 25th June 10:00-11:00 via zoom (information on the application brief)

- Successful projects will be fully costed by Research Services based on the information submitted

Project Title: _____

Lead PI Name: _____

Lead Collaborator/Expert Name (if applicable): _____

Project Costs			
Directly Incurred (DI) costs Please provide a detailed breakdown of all proposed costs. Staff costs should be obtained from BlackDackel. If you are costing existing members of staff, ensure to cost at the correct grade/spinal point and include their name if known.			
BlackDackel Information			
Project ID		**Budget ID**	
Cost type	**Breakdown and description/detail**		**Cost (£)**
Staff Costs Include %FTE, start date and duration, name and grade of staff (if known) for each post costed			
Consumables Provide full breakdown of consumables			
Other * (please specify)			
		Total Costs:	
PI and Co-Is Time commitment Please provide details on the time you and your collaborator will dedicate to this project. This will be approved by your Head of School should your project be successful			**% FTE ****
Principal Investigator			
Co-Investigators			

Please make sure that quotes for any bought in service **includes VAT if applicable*

***For each PI/Co-I please indicate the expected %FTE to be committed to this project. We do not need costs, just an indication of %FTE dedicated to this project.*

This proposal is submitted by Principal Investigator:		
(Date)	(Print name)	(Sign here)

Costings to be estimated using BlackDackel DO NOT CONTACT Research Services

Fill in the Project ID and Budget ID obtained from BlackDackel.

Include only Directly Incurred costs (staff costs, consumables, service or consultancy fees, access to facilities etc.)

You are NOT required to obtain HoS sign off

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Visit our website to subscribe to our **newsletter** and **YouTube channel**, and to find out more about how we can help you progress your translational research

THANK YOU

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C4T
Full application form

'Confidence for Translation' C4T Award: Full Application Form 2024	
PI details	
PI Name	
End date of current contract of employment (only **if the PI is on a fixed term contract**)	
Senior guarantor (only **if the PI is on a fixed term contract)**	
Is the PI a current UoM staff member or holds UoM honorary position? ☐ UoM Staff ☐ Honorary position *If honorary status is yet to be officially formalised, please provide details/timelines and name of a UoM Co-I for post award management.*	If *honorary*, please describe status of the contract: ☐ Current ☐ In progress If *in progress*, please provide: Timelines for obtaining: Name of UoM Co-I:

Post docs can be PI with a senior guarantor as CO-I

Applications from honorary staff as PI are accepted but if contract is not in place a Co-I from UoM is needed

PI Faculty	
PI School/Department/Division	
PI Contact Info	
Collaborators: Names / Faculty / School / Division	
Was this project previously (or currently) supported by external or internal funding (including A2E, CiC, IAA, C4T & P4T)? **Yes** ☐ **No** ☐	*If yes, please provide details on the funder(s) and awards(s) supporting this research:*
References *If you wish to reference your previous work, please add your references here (include doi). Do not reference your own work in the following pages of the application form.*	

Please note that this page will be removed from the proposal when it is sent to peer review t
the review process anonymous. Kindly add a page break after this text.

Evidence of previous successful funding to show work has been peer reviewed already

Please include any references of your own work here and do not repeat in the rest of the application. The proposal should NOT contain any information that can identify you

Don’t forget the title!

C4T Project details		
Title of Project		
Proposed start date and project duration/end date	*Duration:*	
	Start:	
	End:	
Total funds required 100% of directly incurred costs only	*Total:*	
	Staff:	
	Consumables:	
	Other (specify):	

Does your project align with any of the priority areas for the Wellcome trust or NIHR Manchester BRC? **Yes** ☐ **No** ☐ If **yes**, please tick all relevant boxes on the right. If BRC alignment is identified, please complete question 17. If **no**, skip this question. *Please note that this information will only be used to assign reviewers and not to determine the source of funding.* ***Proposals focusing outside these priority areas are also welcome and encouraged.*** *For BRC support we would expect a cross-cluster collaborative project across at least two clusters and evidence of alignment to BRC core strategic aims (details of which can be found in the FAQ document).*	***Wellcome's Health Challenges*** *Read more.*	☐ Mental Health ☐ Climate and Health ☐ Infectious Disease
	NIHR Manchester BRC Clusters	***NIHR Manchester BRC Themes***
	Cancer	☐ Prevention and Early Detection ☐ Advanced Radiotherapy ☐ Precision Medicine ☐ Living with and beyond cancer
	Inflammation	☐ Rheumatic Musculoskeletal Diseases ☐ Respiratory Medicine ☐ Dermatology: Cutaneous Inflammation and Repair ☐ Integrative Cardiovascular Medicine
	Disease Complexity and Multi-morbidity	☐ Next Generation Phenotyping and Diagnostics ☐ Next Generation Therapeutics
	High Burden Under researched conditions	☐ Hearing Health ☐ Mental Health ☐ Rare Conditions

If applicable, highlight alignment with Wellcome's Health Challenges or NIHR BRC Themes

Alignment with Wellcome's Health Challenges or BRC themes is NOT a requirement.

Applications from ALL areas of translational research are welcome

1. Project Summary – please provide a summary of the state of the art leading to this research project including the unmet health, clinical or product development need you are seeking to address. References to be listed in the PI details question on page 2 of this document. (*Maximum 300 words*)

Set the scene, give the big picture and importance

You can include a page of figures with preliminary data.

2. What is your proposed solution to this need? What is the rationale and supporting evidence that your proposed solution will meet the targeted need? You might make use of figures for preliminary data in this box or attached as appendix (these should be under one A4 side). Please avoid using information that might identify you. (*Max 300 words*)

3. Who is the intended end user and/or target market for your proposed innovation? This can be whoever will purchase your product or who will adopt your new intervention or policy. (*Max 200 words*)

Note: your intended end user and the target market may be different.

4. What are the competing solutions (direct or indirect) and their developmental status, and what is the competitive advantage of your proposed solution? (*Max 300 words*)

This is the value proposition, include any relevant health economics information

This is the line of sight to patients – highlight the timeline and what is needed to get to the end point (e.g. multiple grants)

5. How soon would the proposed innovation reach a) patient care or other clinical setting and b) commercial market or other means of distribution? Please explain what additional studies or development work will be required to achieve these endpoints? (*Max 200 words*)

6. Please describe where on the translational research pathway your current research/project sits, and where it aims to go? (e.g. D1 to D2, or T2 to T3) *(Maximum 100 words)*

7. What is the specific hurdle or bottleneck that you need to overcome to progress along the translational research pathway? **Please summarise the critical hurdle within a sentence** and then expand to include further evidence to support your view. *(Maximum 300 words)*

Make this very specific

Speak to Translation Manchester if you are unsure

8. Describe how you will use C4T funding to overcome the bottleneck including details about the project plan, the rationale, the hypothesis, main tasks, methodology - including analysis methods and sample size justification - and expected outcomes. *(Maximum 500 words)*

Make sure the plan addresses the bottleneck and justifies the budget.

9. What are the key milestones in overcoming the bottleneck? Please include timelines and how will you demonstrate they have been met? (Make use of Gantt charts if appropriate) *(Maximum 400 words)*

Make the milestones realistic, include Go/No-go points. Remember to include time for ethical approvals, recruitment and contracts

10. Please identify any risks with the proposed approach and how these will be mitigated. Go/no go points can be identified on timeline / Gantt chart provided in question 9 (*Maximum 200 words*)

Rank risks as low, med or high using a risk matrix (impact x likelihood)

11. Please outline a brief plan for follow on studies, potential industry collaborations and further funding, including targeted funding schemes and deadlines. If you do not have a clinical co-applicant please explain how you have/will gain clinical insight into the translational goals of the project *(Maximum 300 words)*

Don’t just list the grants you will apply for, explain how any follow-on funding will help you achieve the patient end point

12. Do you already have researchers in place to conduct this research? **Yes** ☐ **No** ☐	If Yes, please provide details, including their availability, and were possible a potential 'back up':	
	If No, please outline reasons and include a plan to source the researcher(s):	
13. Does your project include any cross-faculty and/or external involvement (including industry partnerships and NHS). **Yes** ☐ **No** ☐	*If Yes, please tick and specify below:*	
	☐ *Other Faculty*	
	☐ *NHS*	
	☐ *Industry*	
	☐ *Other*	

Project timeline should reflect this

Please highlight any cross faculty, NHS or industry collaborations

14. If you answered yes in **Q13**, will the external organization (EO) receive part of the funding and/or provide in kind contribution? **Yes** ☐ **No** ☐	*If **Yes**, please fill in the information below:*	
	Name of the organisation:	
	Amount Allocated to EO:	
	In kind contribution from EO:	
15. If you are proposing to collaborate with an SME or industry partner, have you been in contact with your faculty's business engagement, and/or contracts teams? **Yes** ☐ **No** ☐	If yes, please name your contacts:	
	Business Engagement	
	Contracts:	
16. Does your study require Home Office Animal License, NHS ethics & governance or any other approvals (e.g. access to data, tissue, software)? **Yes** ☐ **No** ☐	*If yes, when and how will these be obtained? Please name any relevant contacts in BSF or Ethics and governance teams:*	

Project timeline should reflect time needed for contract setup

Discuss your industry collaboration with the BE team

Intellectual property (IP)	
Depending on whether the project will be funded by Wellcome, NIHR Manchester BRC or MRC budgets, different term and conditions will apply. Wellcome awardees will be required to accept Wellcome's standard revenue-and-equity sharing agreement as set out in Wellcome's grant conditions. If funded by the BRC awardees we will be required to abide by the IP conditions of the BRC (see application brief for details). If you have been in discussions with the Innovation Factory around this project, please name your contact below.	
Innovation Factory contact:	
MFT R&I IP contact:	

Do speak with the tech transfer office!

18. Does the proposal have freedom to operate, or does it require access to background IP?
19. Will the project generate new IP? If yes, how will this be managed?
20. Will the project generate new IP that will be owned by an external party (e.g. external project partner)? If yes, how will this be managed?

Are any third parties involved (incl PhD students) ?

Application Checklist	
☐	I completed all questions of the C4T form
☐	Any information that could identify me or my research group has **only** been included in the *PI details* page.
☐	I have completed the Budget Sheet (last page of this document) and included the BlackDackel **project ID** and the **budget ID** relevant to this project.
☐	I confirm that the information on BlackDackel matches the information added to the Budget Sheet.
☐	*Only for projects involving small molecule drugs*: The project tractability section of the MRC DPFS small molecule information form is clearly covered in the main C4T application form, **OR** I have completed and attached the MRC DPFS small molecule information form to this application
☐	I have deleted the first page of this document (i.e. description of the application process), and saved the rest of the file as PDF, using PI Name_Surname as filename prior to submitting to translation@manchester.ac.uk.

You will have to completed the costing using BlackDackel

Submit your application by 12:00pm on 10th of July

Project Title: _____

Lead PI Name: _____

Lead Collaborator/Expert Name (if applicable): _____

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TPP

Target Product profile (TPP)

- A tool to help you identify and clarify the translational potential of your innovation
  - If successful it will be a condition of the award that you complete a TPP prior to your kick off meeting, in which panel feedback is provided to help ensure the project reaches its translational potential.
  - For many follow on funding opportunities e.g. DPFS you may be required to complete a TPP
- Incorporate TPP-style thinking and information into your C4T full application

What is a TPP?

- Definition from MaRS Discovery District Innovation Hub, Toronto:

> **What is a target product profile?**
>
> A target product profile (TPP) is a key strategic document that provides a summary of the following:
>
> - the product under development
> - the product's desired characteristics and features
> - the studies and activities that must be completed to demonstrate the product's performance, efficacy and safety
> - the features of the product that provide a competitive advantage
>
> A well-designed TPP provides a structure to ensure that a company embarks on a product development program that is efficient and yet defines a listing of all relevant medical, technical and scientific information required to reach the desired commercial development outcome. Historically, the US Food and Drug Administration (FDA) developed the concept of a TPP to facilitate the communication strategy regarding a particular drug development program. However, many of the objectives provide sound guiding principles for the development of diagnostic products or medical devices.

Characteristics of a TPP

- **Indications:** Which diseases?
- **Population:** Which patients and where?
- **Clinical Efficacy:** Does it kill the parasite effectively?
- **Safety and Tolerability:** What kind and how many adverse events?
- **Stability:** How long can it be stored in the field?
- **Route of Administration:** How is it given to patients?
- **Dosing Frequency:** How often and how long must it be given?
- **Cost:** Will it be affordable to target population?
- **Time to Availability:** How long will it take to develop?

Who are you competitors and/or current solutions?

The importance of understanding the external landscape

If your project is addressing an unmet medical need there WILL be alternative solutions.

The product will also need to compliment, enhance or change current clinical practice.

For some products cost is likely to be a consideration.

TPP example (1)

Product Properties	Minimum Acceptable Result	Ideal Result
Primary Indication	Relief of pain symptoms in diabetic neuropathy	Relief of symptoms in neuropathic pain syndromes
Patient Population	Adults with diabetes who experience neuropathic pain	Adults and children with neuropathic pain
Treatment Duration	Chronic	Chronic
Delivery Mode	Oral	Oral
Dosage Form	Tablet or capsule	Tablet or capsule
Regimen	1–2x/day	1x/day
Efficacy	A 40% decrease in pain score in 30% of patients	A 70% decrease in pain score in 50% of patients.
Risks/Side Effects	Devoid of opioid side effects Devoid of GI side effects from Non-steroidal anti-inflammatory drugs (NSAIDs) Minor or moderate CNS side effects	Devoid of opioid side effects Devoid of GI side effect from NSAIDs No CNS side effects

TPP example (2)

	CMML Target profile (single agent)	**WP**
Efficacy and patient selection	1) ORR (IWG criteria) >75% by week 8, with a median response duration of >12 months in unselected CMML population OR 2) ORR >80%, in patients with >median CCR2 expression on BM and blood CMML blasts.	2a-d 6a-d
Tolerability	Low immunogeniity (assessed by anti-drug Abs) and with no grade 3/4 non-hematological toxicities in patients. No dose-limiting inflammation at injection site. No evidence of non-hematological toxicity at <30-fold efficacious exposures in preclinical models.	2b 3 6a 7a-c
Administration	Once weekly dose of <100 mg total dose by <30 minute iv infusion.	2b, 2d 6a-c
Pharmaceutical properties	Chemically and physically stable drug formulation (as solution or lyophilised powder) in standard iv compatible formulations. CMC approach (including cost of goods) consistent with related ADCs in clinical development.	1a-c 4 5a/b