Wellcome Trust Institutional Translational Partnership Award (iTPA)
University of Manchester
Access To Expertise (A2E) 2019

The University of Manchester has been awarded Wellcome Trust (WT) funding in the form of an Institutional Translational Partnership award (iTPA).

The funds are intended to accelerate the transition from discovery research to translational development by unblocking specific translational research bottlenecks. We have identified that accessing appropriate expertise in a timely manner can be a barrier to translation, hence we have initiated a pilot scheme in an attempt to address this problem. The Access to Expertise award aims to enable investigators to access necessary technical expertise (external to their immediate research group) in order to reach higher technology readiness levels or shift their research to the next phase in the translational research continuum (Appendix 1).

The scheme is not intended to fund an entire project, <u>but to support expert engagement with ongoing projects, to overcome a particular barrier to translation which needs addressing</u>. See Appendices 2 and 3 for examples.

We anticipate award duration being typically ~ 6-9 months but will consider up to maximum 12 months. Due to this being charitable funding, costs will be provided for 100% of Directly Incurred costs only, up to £25,000. Due to the short timeframe, it is highly recommended that projects which already have experts in mind and are primed to start, apply.

The iTPA scheme is not limited to the development of new chemical entities; all modalities of therapy and diagnostic are welcomed, including engineering/medical technology, utilisation of digital healthcare technologies, and bioinformatics approaches.

The proposals must demonstrate that use of this award would progress research along the translational continuum.

The WT and UoM wish to promote academic-industry interactions (including SMEs) through the iTPA scheme; applicants are therefore strongly encouraged to explore how awards could be used to develop these interactions. We also encourage interdisciplinary proposals, including cross-faculty collaborations. Where possible, please look to source expertise from within UoM and associated NHS Trust partners.

Please note that investigators are strongly advised to consult with a clinician on the medical aspects of these translational projects, if appropriate.

All proposals <u>must</u>:

- **Progress research along the translational research continuum**
- **Overcome a clear research hurdle**
- **Have a clear plan and timescale**

The funding will not support:

- Fundamental research
- Entire translational projects
- Projects with no clear translational agenda or applied outcomes
- Staff between posts/funding (i.e. as "bridging" funds), or PhD studentships
- Continuation of normal research grants

Applicant eligibility

The lead applicant's contract of employment should exceed the duration of the proposed A2E project, and a potential follow on project, prior to application to the A2E scheme. Applications are welcomed from both UoM researchers and partner NHS Trust clinicians.

Finances

As the iTPA is a 2 year pilot scheme, strict adherence to spending regulations will be mandatory for successful applicants. Expenditure will be permitted to the end of the agreed time-frame for the project (i.e. last date of project). No spending will be permitted after this date. Clearance of invoices will be permitted for 3 months after the project end date.

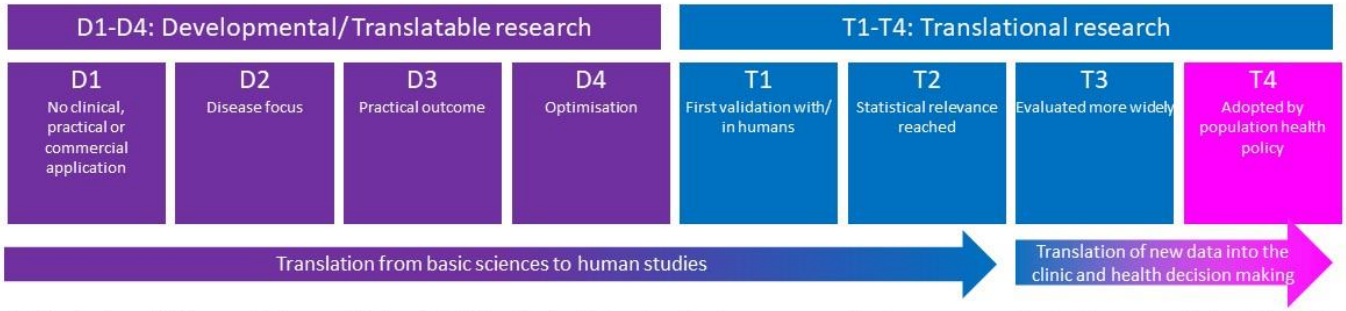
Reporting

Successful applicants will be required to submit brief informal monthly updates outlining study progression and outputs to the Translational Research Facilitators, to ensure projects are kept on track and support can be given if needed.

Application process and timeline

- **Application form (2 page) will be available to download from the website from Monday 4th March 2019.**
- Applications must be submitted to Research Support Managers by Friday 29th March 2019.
- **Deadline to submit applications: Tuesday 30th April, 12 noon.**
- Applicants will be notified of outcome on 27th May.
- **Projects will be expected to start in early June.**

Appendix 3. The Translational Pipeline



D1: Pure basic research to gain knowledge	D2:disease-related or oriented/ strategic research: To obtain new insight or a starting point for diagnosis, treatment or prevention.	D3: when the initial outcome of D2 research has been identified and its link to the disease has been confirmed	D4: when the target from D3 is manipulated to confirm disease association.	T1: when a new method or treatment is first validated in humans	T2: when a statistically relevant number of patients demonstrate the efficacy of the new approach	T3: when the new approachis being tested more generally	T4: translating findings to population health
	Examples: Genomewide association studies for disease-related genes. Epidemiological studies to identify links between environmental factors and disease. Establishing connections between imaging data and disease. Correlating genomics or proteomics and disease.	**Examples:** target molecule or metabolic pathway identified and confirmed	**Examples:** Identifying a small molecule that alters target activity in a model system. A diagnostic system based on a biomarker. Stimulation or blocking of an immune response.	**Examples:** Phase 1 clinical trial First use of a device in a small target population First use of software in a clinical validation study Initial validation of a lifestyle intervention	**Examples:** Phase 2 and 3 clinical trials Greater number of patients testing a device or lifestyle intervention Multiple clinical sites using newly developed software	**Examples:** Phase 4 trials Use of device or intervention being routinely used Software identified as superior to existing tools	**Examples:** Adoption into policy and/ or guidelines as a routine method or approach

Gannon, F. EMBO reports **15**(11); 1107-8. 2014. DOI 10.15252/embr.201439587

Appendix 2. iTPA background and A2E scope

iTPA Aims

- Building better links between science, technology and innovation
- Removing barriers between disciplines and making it easier to take the first translational leap
- Supporting and enabling innovation
- Improving knowledge transfer and building interdisciplinary programmes across Health Innovation Manchester

iTPA Background

As a result of a survey conducted with Wellcome Trust funded investigators, several common barriers to engage in translational research were identified. These are summarised below:

- The coordination of clinical sample collection, ethical approval and access to patient characteristics and demographic data. This requires specialised expertise that links the University with Greater Manchester NHS trusts. Many existing sample or data collections have been collected for specific purposes and there is a need to make such collection more 'open' and available for researchers.
- Communication limitation between bioinformaticians/biostatisticians and research laboratory staff. This requires bioinformaticians/biostatisticians to be embedded within research groups.
- Access to a regulatory network that would advise on regulatory approval process; access to technical expertise to help scoping market for technology commerciality.
- Multidisciplinary and collaborations are crucial for the successful conduct of translational research: more collaborations between clinicians and fundamental researchers are required in addition to better links with engineering and physical sciences.

The iTPA 'Access to Expertise'

The iTPA Access to Expertise award will allow researchers to overcome these key problems, by enabling:

- Access to appropriate **technical expertise**; for example,
  - Second bioinformatics/biostatistics expertise or time to maximally capitalise on large data sets
  - Buy out dedicated time for trials physicians and nurses to interact fully with academics, and for academics to spend time in a clinical setting
- Access to complex and specific **regulatory advice**
- Recruitment of external **mentors/entrepreneurs** in residence to guide academics in engaging with translational research with tailored routes to clinic/market
- Secondment in a **clinical or industrial environment**
- Analysis of **market/patient need** and competitive landscapes

This list is not exhaustive, and other methods of overcoming research challenges by accessing expertise will also be considered.

Appendix 3. Examples of previous winners (2018)

Case study 1: Research Nurse required for obtaining human tissue

"My lab has been interested in determining how the immune system is regulated, and how this goes wrong in inflammatory disease. The use of mouse models has been fundamentally important in our work, but it is crucial that findings in mice are translated to determine how identified pathways are altered in human disease. However, obtaining clinical samples can be challenging, with help from research nurses essential in identifying potential study participants, sending out study information, consenting patients on the day of their procedure and co-ordinating obtaining the samples from the clinician. One major challenge is acquiring the funding for the research nurse. This can be requested as part of normal grant applications, but if samples are required quickly to help finish off a study, things can be difficult.

In our case, last year we submitted a paper to a high-impact journal, which got favourable reviews but with requests for additional experiments requiring human intestinal samples. However, funding for obtaining such samples had just lapsed. The Access to Expertise call came at an ideal time, which allowed us to apply for short-term funds (6 months) for a research nurse. This allowed us to perform the necessary experiments, and successfully publish our paper."

Award duration: 6 months
Costs: 5% Study co-ordinator, 32% Research Nurse, 5% Consultant time

A2E 2018 Awardee; Mark Travis, Professor of Immunology (UoM)

Case study 2: Augmented Reality expertise required for app development

"Within the domain of preventive mental health for children and young people, management of self-harm is a top priority. Self-harm among young people is increasing and is the biggest risk factor for suicide.
CAMHS.Digital wanted to co-produce an innovative digital solution for self-harm self-management with and for young people using Augmented Reality. We had produced initial evidence that a self-harm self-management app 'mSootheBox' could be effective in creating distraction techniques for children and young people who self-harm, especially at times when services are scarce (i.e out of hours and late at night when children feel alone). However, we were blocked from moving the research forward by a lack of Augmented Reality expertise. The Access to Expertise award enabled us to co-design the app with Augmented Reality industry experts, Sparta Digital and most importantly, young people, in interactive workshops. The award funded 4 workshops with young people and 1 roadshow event demonstrating the designs to key mental health stakeholders. We are currently half way through our funding, but success has already been evident by the enthusiasm of the young people and interest from a large mental health charity, who wish to fund further development of the app."

Award duration: 9 months
Costs: Workshop tools, Digital consultancy, Stipend for workshop participants

A2E 2018 Awardee; Kathryn Abel, Professor of Psychological Medicine (UoM/MFT)