TranslationManchester

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@Translation_Mcr

Dr Fiona Foster
Dr Alessandro Faroni
Translational Research Managers

MANCHESTER 1824
The University of Manchester

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Translational Funding
"Valley of Death"

GOVERNMENT FUNDING FOR BASIC RESEARCH

TRANSLATIONAL FUNDING

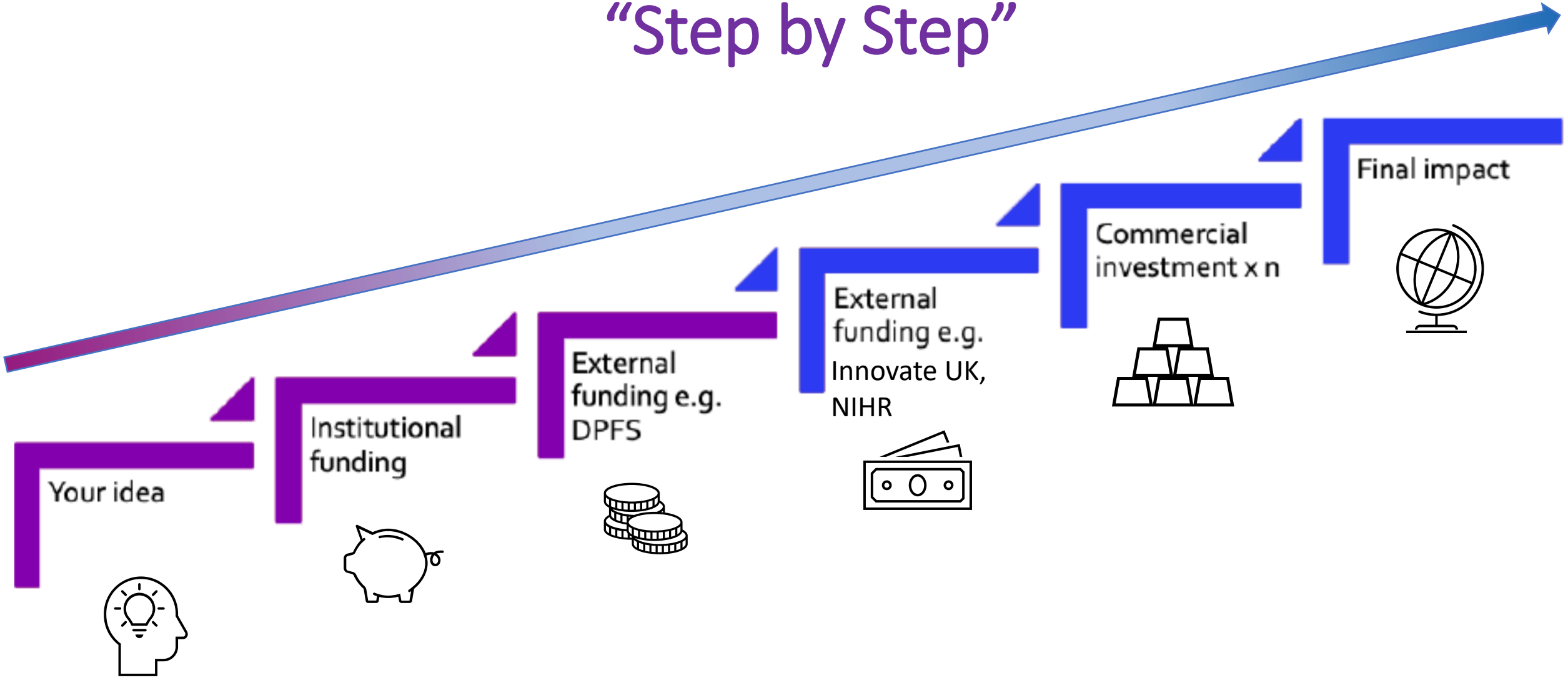
COMMERCIAL FUNDING

D1 | D2 | D3 | D4 | T1 | T2 | T3 | T4

Experimental Research | Applied R&D | Technology Implementation

Adapted from CIIT/University of Oxford 2021/Courtesy of Nessa Carey

Funding Translational Research
"Step by Step"



Adapted from CIIT/University of Oxford 2021/Courtesy of Nessa Carey

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Accelerator Awards

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Access 2 Expertise

TranslationManchester

Confidence 4 Translation

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UKRI Medical Research Council

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TranslationManchester
Access 2 Expertise

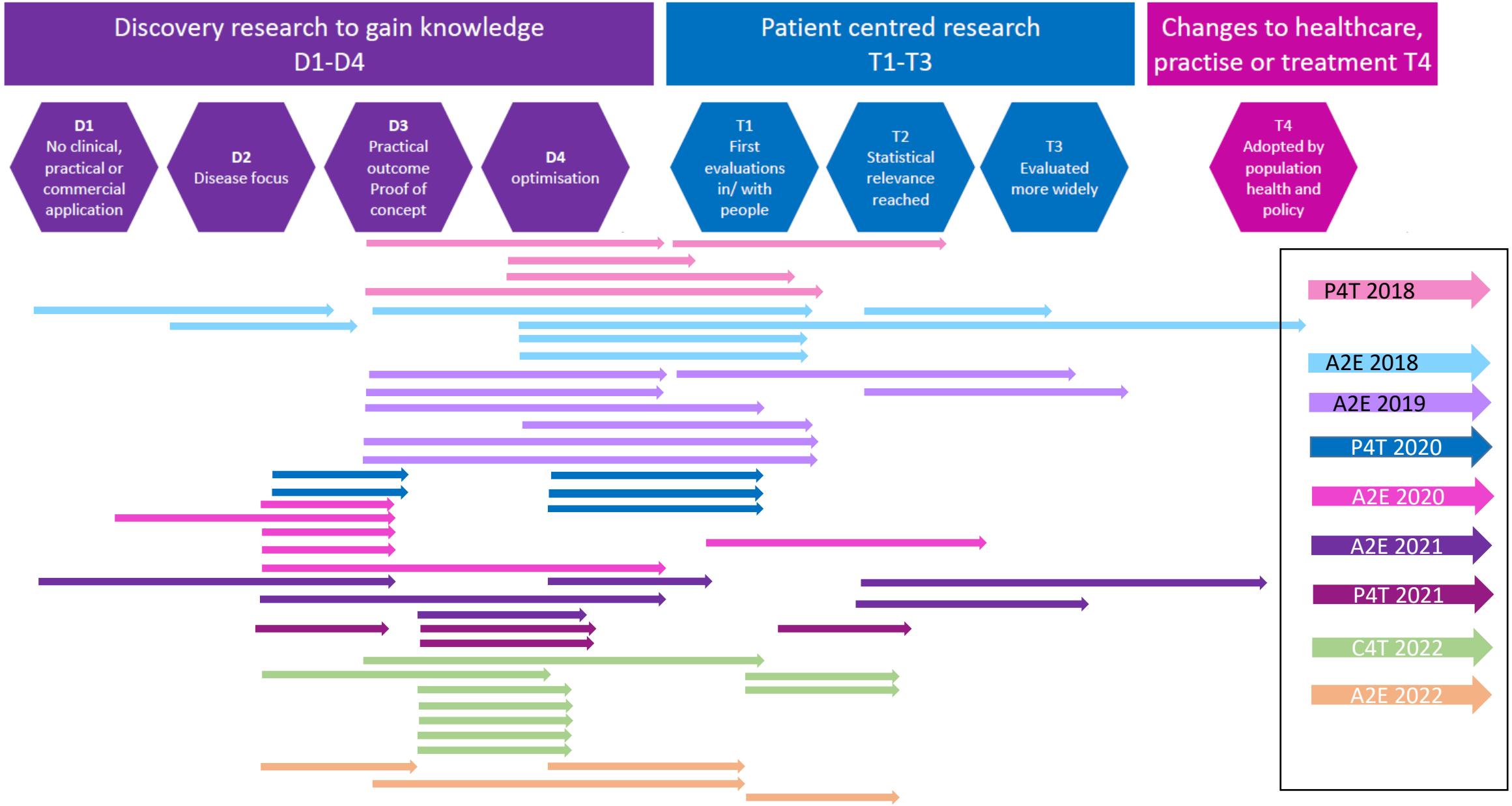
- Engage technical expertise external to their immediate research group
  - Bioinformatics/biostatistics
  - Research nurse
  - Software/app design
  - Regulatory advice
- Designed to overcome a bottle neck or hurdle, max. **£25k,** 6-9 months duration
- Salary or consultancy costs, not consumables focused

Next call opens early 2023

TranslationManchester
Confidence 4 Translation

- Overcome a specific hurdle or bottleneck that is preventing progression along the translational pathway
  - Prototype manufacturing
  - Proof of concept
  - Patient centred research
  - Collaborating with industry
- Designed to overcome a bottleneck or hurdle, max. **£75k,** 6-9 months duration
- Salary and consumable costs

Next call opens spring 2023



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Funding Schemes

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TranslationManchester
Funding Schemes

New Schemes coming in 2023

Coming in 2023

TranslationManchester
Innovation Labs

TranslationManchester
ECR Competition

TranslationManchester
Access 2 Tissues

TranslationManchester
Innovation Labs

- Half day workshop to fund **new collaborations between academics and industry** partners.
- Themed facilitated workshops to address a business challenge with academic expertise.
- Round table discussions, **pitching of ideas** at the end of the session to **win seed funding** to kick start the collaboration.
- **£60k per year from the TPA budget to fund 3 -4 projects each year.**
- Delivered by Translation Manchester, FBMH Business Engagement and Innovation Factory.
- First workshop in 2022- Digital Health & AI- 4 new projects funded.

Second Innovation labs coming May 2023

TranslationManchester ECR Competition

- Previously delivered via Research Collaboration Funds managed by **CARD**.
- **9 projects** funded since 2021 with applicants achieving significant outputs such as **tenure (2X)** or **MRC CDA fellowship**.

- Promote **translational research** culture in the Early career Researchers Community.
- Fund independent small scale projects to gather pilot data for **fellowship or grant applications**.
- We will fund up to **9 projects at £5k each**.

Next call opens spring 2023

TranslationManchester

Access 2 Tissues

- A one off call.
- **£30k** total budget for 3-6 projects (**up to £10k** each)
- To facilitate the acquisition of tissues from **Biobanks that are part of the TMRN**.
- Academic led (**1 submission per PI**)
- Requires **Biobank sign-off** (they can support several PIs)
- Opens **Early 2023**, further details on our website soon.

Translational Research Manchester 2022

Progress your translational research with the support of our network

Scan to complete the translational bottlenecks and event feedback survey

@Translation_Mcr

#TranslationMCR22

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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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Knowledge Exchange Partnerships Team, UoM

KE Funding Mechanisms

Joanne Summers, KE Manager

The KE Partnerships Team - Role

We manage the delivery of the UKRI Impact Acceleration Account (IAA) and the University's Innovate UK Knowledge Transfer Partnership (KTP) portfolio.

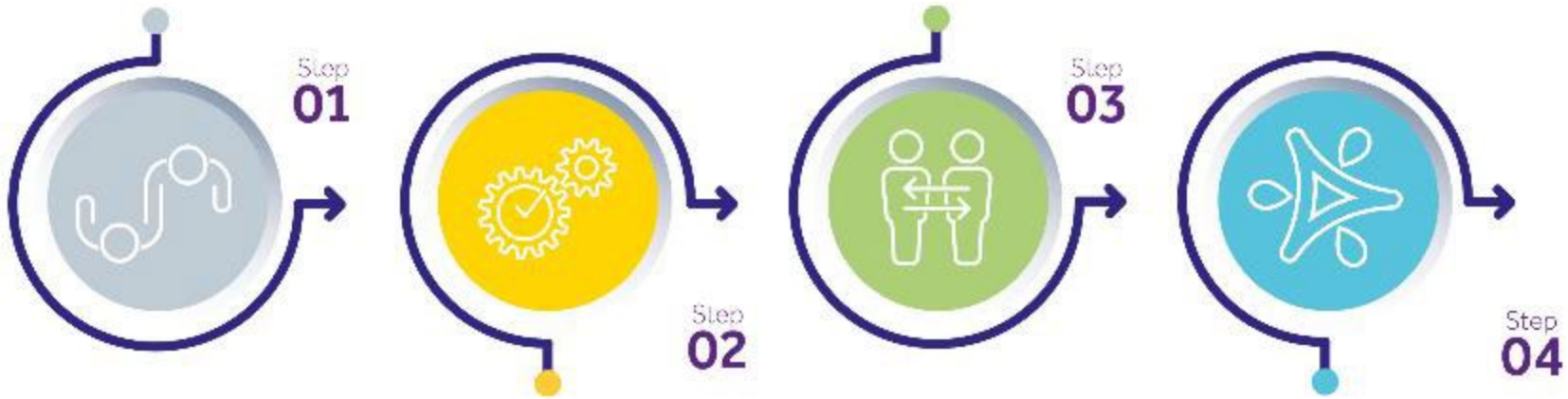
The team utilises the funding to support the creation of impactful collaborations between the University and external partners for mutual benefit.

KE partnerships co-develop, co-deliver and embed solutions.

Types of KE Projects

1. Relationship Development – IAA

3. Secondment - IAA



2. Proof Of Concept - IAA

4. Knowledge Transfer Partnerships (KTP)

> KTP
> mKTP (Management)
> AAKT (African Agri Tech)
> AKT2I (Short Accelerated projects)

IAA - There are 3 ways to get involved:

UK Research and Innovation

1. Relationship Development

Aims to foster and build new relationships to create opportunities for collaboration and exchange of knowledge and skills between external organisations and academics

(typical duration 6 mths part-time, up to £10k, open call)

2. Proof Of Concept

Support for the very early stage of transforming research expertise into impactful opportunities with external partners.

(typically 6 – 9 mths, up to £30k grant – submission deadlines apply)

3. Secondment

Provides flexible support for secondments between the University and external partners to focus on the creation and development of impactful outcomes

(typically 12-18 mths, up to £60k grant – submission deadlines apply)

Eligible collaborators are UK-based businesses (including UK sites of international businesses), UK charities, and UK public sector organisations such as the NHS.

Current call closes 07/12/22. **Call document -** display.aspx (manchester.ac.uk)

KTP: Knowledge Transfer Partnerships

3 – Way Partnership

The Business
+
The Academic
+
A KTP Associate is recruited to deliver an innovative, business-led project of clear strategic relevance within the business, co-supervised by the Academic Team.

Grant Rates

Innovate UK will contribute **67%** of eligible project costs for UK based **SMEs**,

50% for large companies

and **3rd sector receive 75%.**

SMEs based in Wales will receive 75% grant until March'23.

What does a KTP support?

A KTP project could deliver **improvements** to existing products or services, support the **development** of novel products and systems.

Or **create frameworks or new ways of working** to **improve productivity** and **upskill** staff.

Project must deliver economic impact for the business

Project duration 12 – 36 months and can be in any research discipline or sector.

Public Sector is not eligible **Submission points every 8 weeks**

IAA Case Study example

Innovative PPE respirator developed to assist in the fight against COVID-19

Collaboration between Staff in the Intensive Care Unit at Wythenshawe Hospital, part of Manchester University NHS Foundation Trust (MFT), School of Engineering and consultancy firm Designing Science Ltd have developed Bubble PAPR, a Powered Air-Purifying Respirator (PAPR), to keep healthcare workers safe during the COVID-19 pandemic.

A patent has been filed and the development team are now working with manufacturing partners to produce Bubble PAPR in large volumes and signing up distribution partners.

How can we support partnerships?

1 CONNECT
Identify and develop relationships with relevant academic experts.

2 COLLABORATE
Work together to scope and shape your project.

3 FUNDING
Work with us to develop a grant application that will part-fund your project costs.

4 RECRUITMENT
Well work with you to recruit a high calibre researcher to lead your project, supported by an academic team.

5 LAUNCH
Work as a partnership to deliver your project with ongoing and dedicated academic engagement.

6 SUPPORT
We will provide support throughout the lifetime of your project and your incredible innovation journey.

MANCHESTER 1824
The University of Manchester

Key Contacts:

Joanne Summers
Knowledge Exchange Manager

joanne.summers@manchester.ac.uk
Or
kepartnerships@Manchester.ac.uk

For additional information please visit:
https://www.staffnet.manchester.ac.uk/rbe/beke/knowledge-exchange/

LifeArc Translational Funding

Translational Research at Manchester 2022

Dr Laura Stennett
Business Manager, Technology Transfer

lifearc.org

16th November 2022

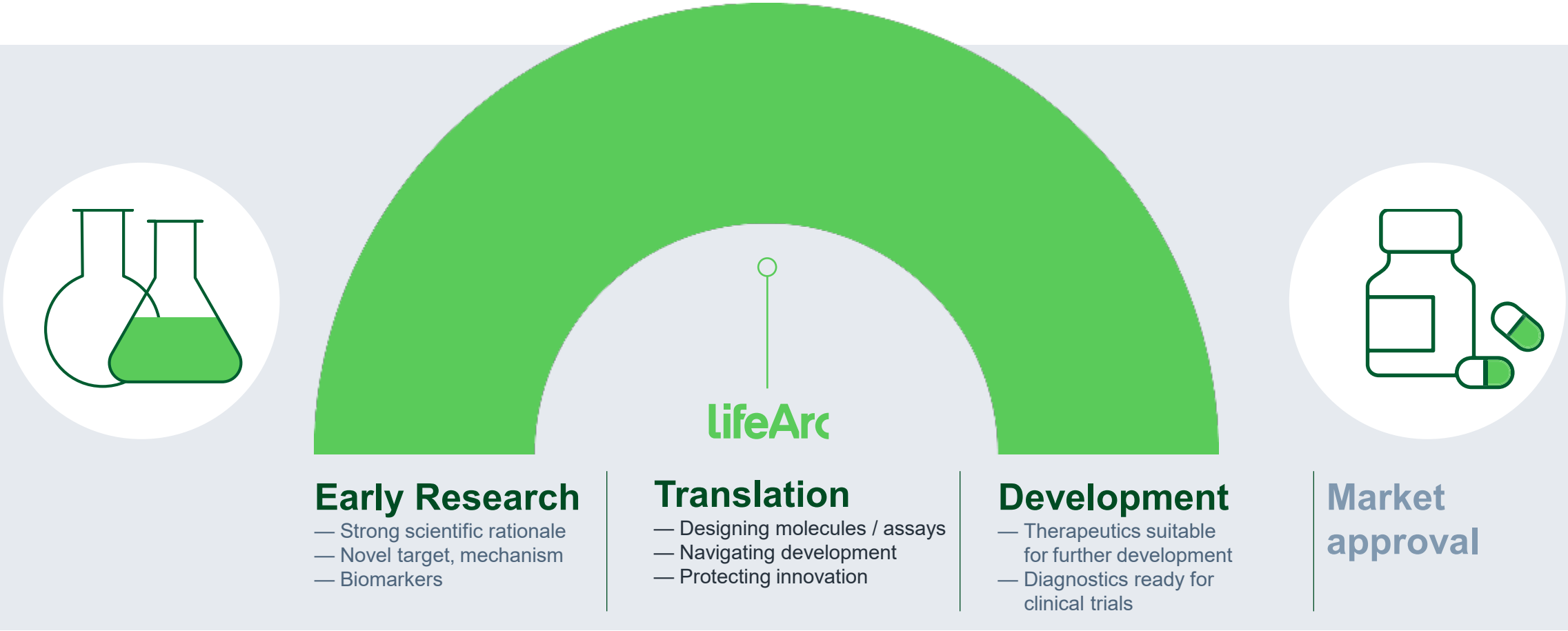
Who we are

LifeArc are the early-stage translation specialists.

We are a self-funded charity focused on advancing early scientific discoveries to a point where they can be developed into the next generation of diagnostics, treatments and cures.

Bridging the gap between the lab and patients

Life sciences research is full of exceptional ideas that have the potential to transform healthcare. The challenge is that many never make it out of the lab.

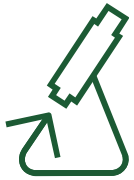


How we work: expertise in translation

Translational advice

Technology transfer support and advice for researchers, charity partners and the MRC:

- Protecting and managing IP
- Translational potential of research portfolios
- Funding, the development path and routes to market



Translational science

- Laboratories in Stevenage and Edinburgh, and a dedicated team at Francis Crick Institute
- Advancing research into early-stage drug discovery: from validating drug targets to developing molecules
- Collaborating on assay design and development and clinical validation for diagnostics

Translational funding

- Addresses some of the financing gaps in the translational journey
- Pre-seed to venture support
- Help to de-risk opportunities
- An integrated funding model for biomedical sciences

Translational funding

We give life science innovators the financial resources to progress their work so that more of it can ultimately reach patients

Philanthropic Fund

Provides grants to researchers for advancing new treatments for rare diseases.

By incubating and de-risking projects, we aim to make investment in therapeutics for rare diseases more attractive.

Pathfinder Awards

Awarded to 6 Universities across the UK with a track record in excellent rare disease research

Funding for internal early-stage projects focused on rare diseases.

Gene Therapy Innovation Fund

£5m annual fund to develop gene therapy technologies from preclinical through to early exploratory trials.

Early Venture funding

Seed and Series A investment in companies working on preclinical and clinical therapeutic development.

Philanthropic Fund

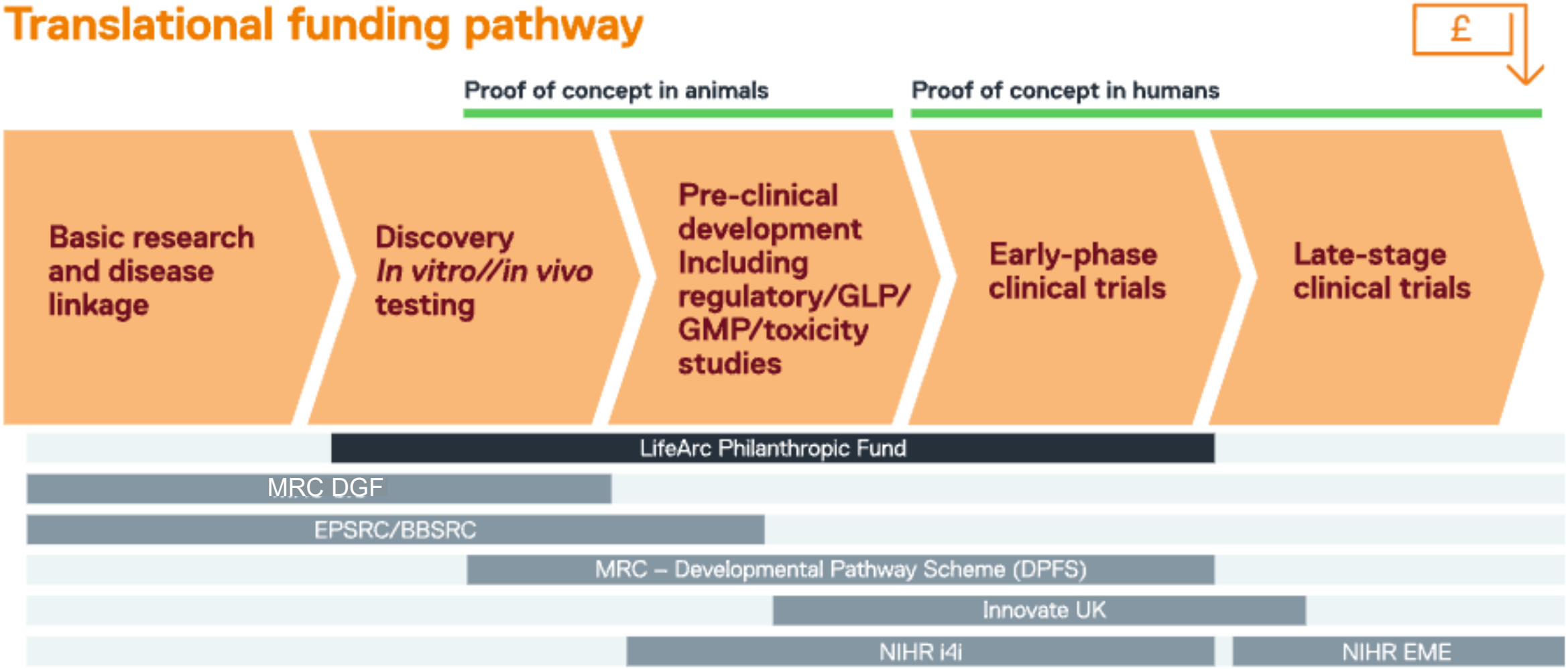
Grant funding for UK-based academics to advance new treatments and diagnostics for rare and ultra-rare diseases.

Projects must:

- Address a rare disease unmet medical need
- Have strong scientific rationale
- Be target-driven projects with SMART milestones and a credible delivery plan
- Have a clear route to patients
- Have, or will have, Intellectual Property to secure the route to patients.

Philanthropic Fund

Translational funding pathway



LifeArc Pathfinder Award

- £500,000 awarded to six UK Universities
- Funding for internal early-stage projects with a focus on translational development in rare diseases.
- Pump-prime ~5 translational research projects with impactful potential

Rare disease research in Manchester

Identify and progress rare disease research happening at the University of Manchester and encourage others to move into the space.

Build capacity in rare disease space

Support the development of a translational culture in the rare disease space and build capacity for future Rare Disease Centres.

Translational Research Applications: Top Tips

Unmet Medical Need

Consider current clinical pathway and the added value of the technology

Rationale

Why will your solution work?

Target Product Profile: linking need to rationale

Success criteria and milestones

Incorporate clear, achievable SMART milestones

Deliverability

How will the project be conducted and by who?

Project team must contain all necessary expertise.

Route to patients

Regulatory considerations

Competition?

Access to future funding?

IP and FTO

LifeArc

Making life science life changing

Thank you for listening

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Engineering and Physical Sciences Research Council

EPSRC Translational Research Funding

Katherine Freeman
Senior Portfolio Manager, Healthcare Technologies

Translational Research at Manchester
16th November 2022

Content

- UKRI and EPSRC Context
- Healthcare Technologies at EPSRC
- Impact and Translation Toolkit
- New strategy and PPIE
- Funding Opportunities
- Hints and Tips

Engineering and Physical Sciences Research Council

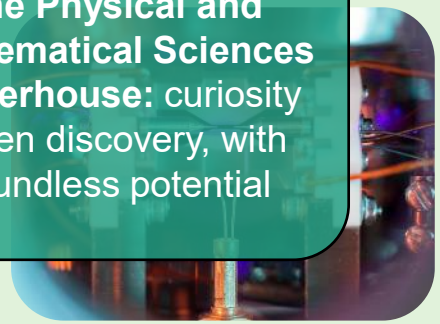
UK Research and Innovation

We work with the government to invest over £7 billion a year in research and innovation by partnering with academia and industry to make the impossible, possible. Through the UK's nine leading academic and industrial funding councils, we create **knowledge with impact**.

EPSRC's 8 Strategic Priorities

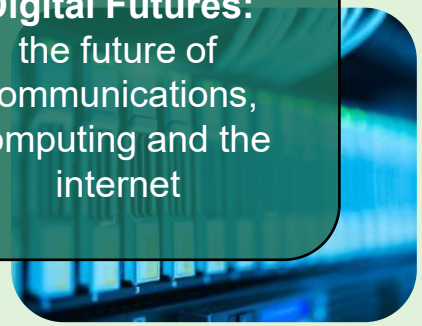
Discovery-led Research

The Physical and Mathematical Sciences Powerhouse: curiosity driven discovery, with boundless potential



Frontiers in Engineering and Technology: unleashing our productivity potential

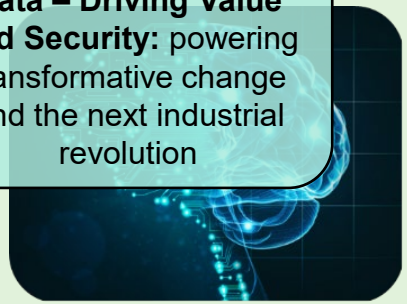
Digital Futures: the future of communications, computing and the internet



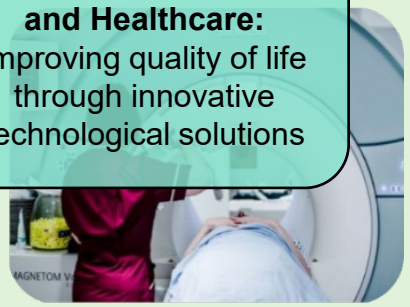
Mission-Inspired Research

Engineering Net Zero: decarbonising our economy and society, creating an alternative energy future & developing truly circular economies

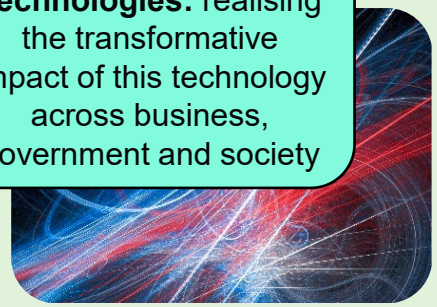
AI, Digitalisation and Data – Driving Value and Security: powering transformative change and the next industrial revolution



Transforming Health and Healthcare: improving quality of life through innovative technological solutions



Quantum Technologies: realising the transformative impact of this technology across business, government and society



International | **Talent and Skills** | **Place** | **World Class Infrastructure** | **Impact** | **Business Engagement**

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An Effective Ecosystem for Engineering and Physical Sciences

EPSRC Healthcare Technologies Overview

£404M

Support from project partners across the Health portfolio

£53M

Support from project partners within Healthcare Technologies

>£75M

Leverage through cofunding partnerships

UK Research and Innovation

CANCER RESEARCH UK

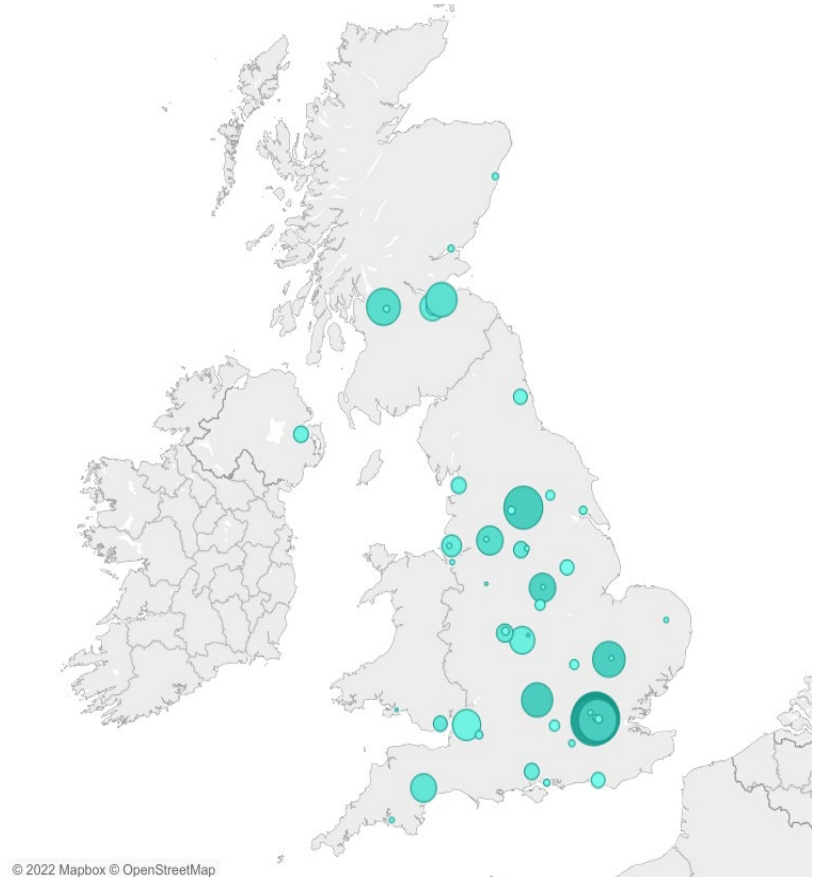
wellcome

Department of Health & Social Care

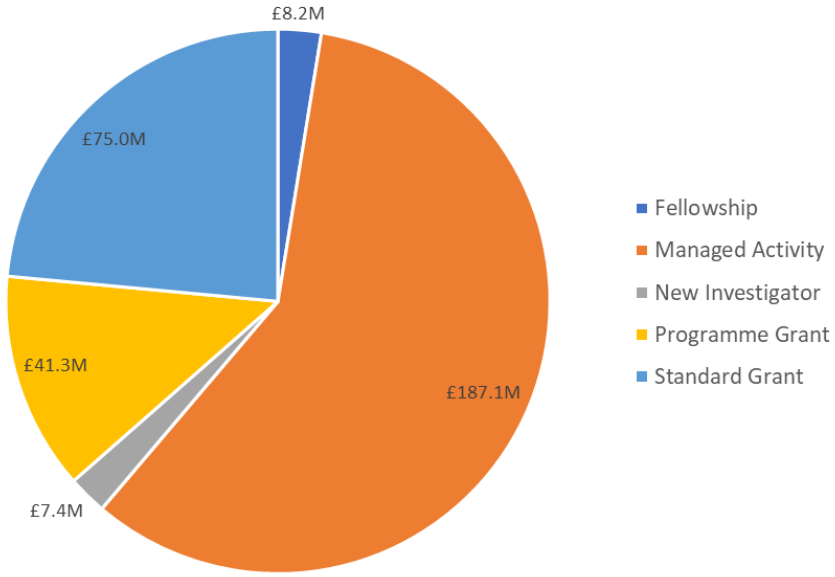
NC 3Rs National Centre for the Replacement Refinement & Reduction of Animals in Research

Engineering and Physical Sciences Research Council

Map of our HT current investments



Healthcare Technologies Current Portfolio April 2022



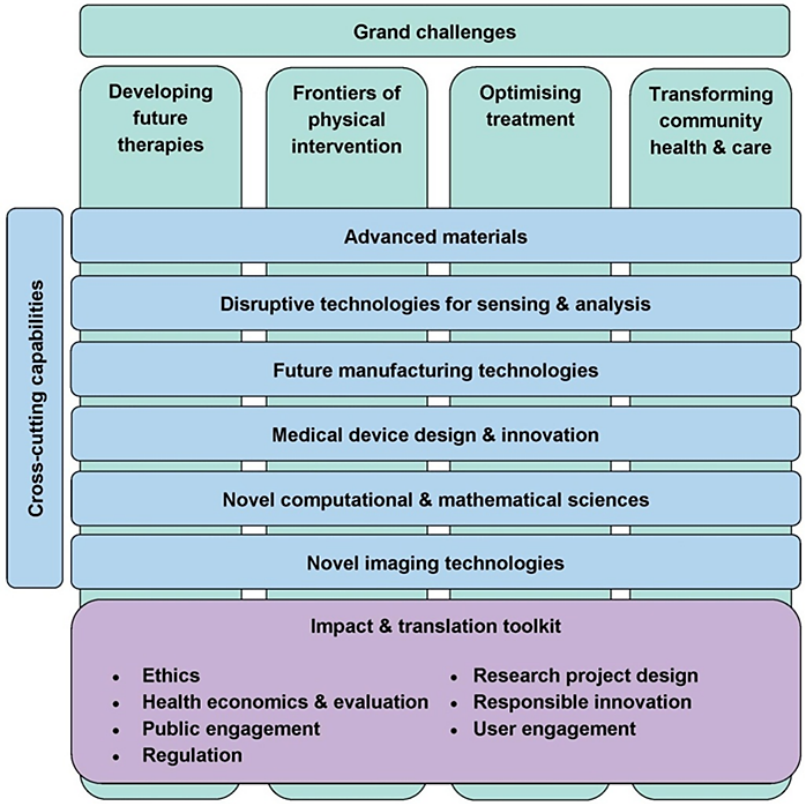
£896M

Value of EPSRC Health Portfolio

Healthcare Technologies in EPSRC

Build critical mass around UK research strengths in engineering and physical sciences that underpin healthcare

Flexible funding to support emerging new ideas and target new opportunities

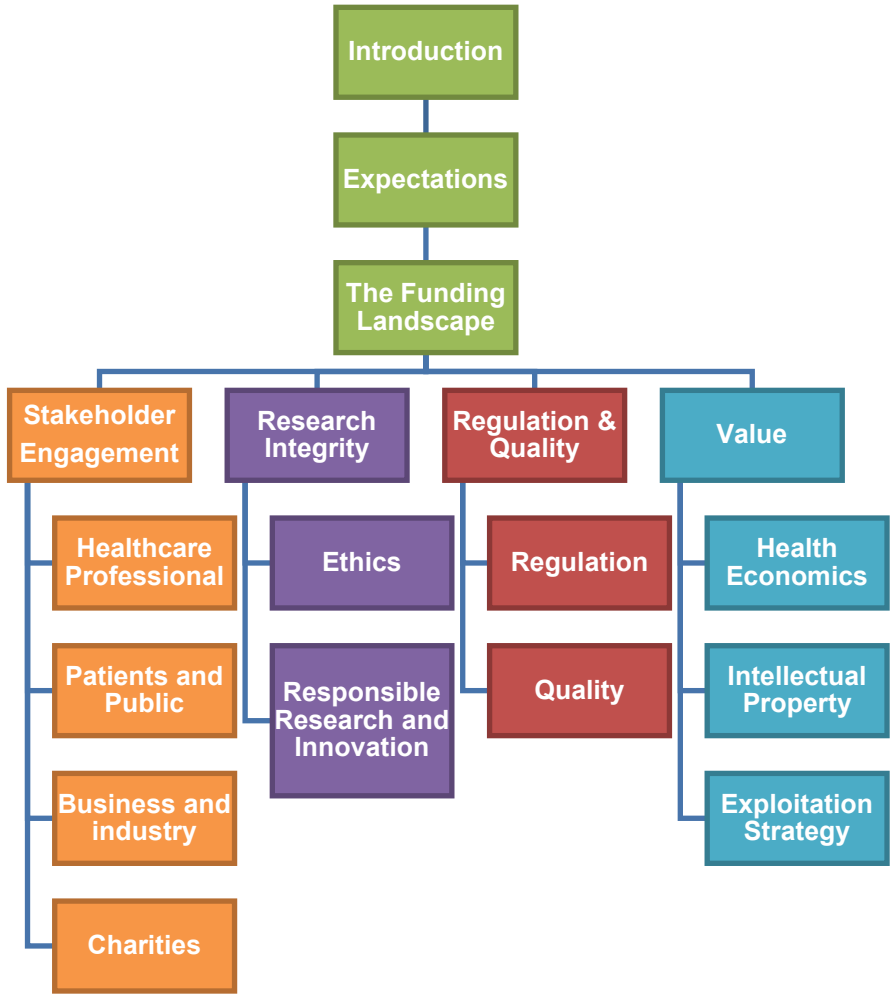


Maximise industrial, and health professional involvement and increase translation to products / practices.

Work in partnership to develop synergies and open up new directions

Impact and Translation Toolkit

- *Draw attention to some of the issues associated with key topics Suggest things to consider when preparing a proposal.*
- *Highlight resources that can be requested from EPSRC.*
- *Signpost additional relevant information.*



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https://epsrc.ukri.org/research/ourportfolio/themes/healthcaretechnologies/strategy/toolkit/

Healthcare Technologies Strategy Refresh

- To respond to advice and changes to the healthcare landscape since the original strategy
- Introductory webinars, survey and workshops (over 400 attendees) to gain community advice
- Workshop themes:
    - Managing Long Term and Chronic Conditions
    - Prediction and early diagnosis
    - Treatment and Therapeutics
    - Sustainable Health care
    - Prevention
    - Mental Health
- Draft strategy for refinement and consultation on the website

https://www.ukri.org/publications/draft-epsrc-healthcare-technologies-strategy-for-consultation/

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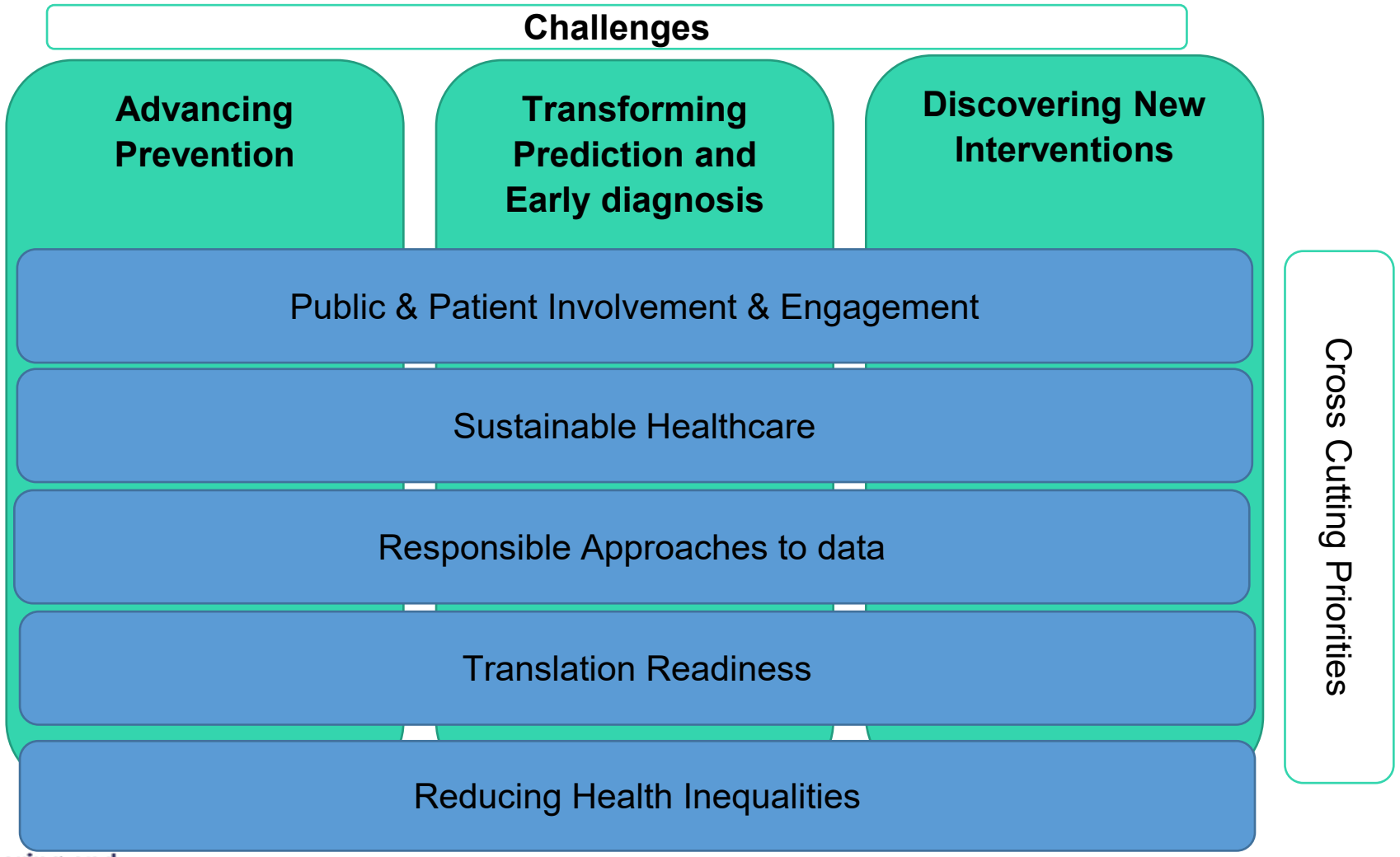
New Strategy



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PPIE in Healthcare Technologies

- Excellent public and patient involvement is an essential part of healthcare research and has been shown to improve both its quality and impact.

- PPIE is important, expected and possible in all types of healthcare technologies research and provides an active route towards developing better quality research

- We aim to support research which demonstrates a commitment to excellent public and patient involvement.

- UKRI has signed a new shared commitment to **improve public involvement in health and social care research.** This brings together a host of organisations including **funders, regulators and research organisations** who play an important role in the UK health and social care

UKRI Engineering and Physical Sciences Research Council

Aims

- To support research in the healthcare technologies space which includes embedded PPIE
- Commitment to share and promote guidance e.g. the UK Standards for Public Involvement
- Building and sharing the evidence of how to involve the public and the impact this has
- Supporting improvements in equality, diversity, and inclusion in public involvement

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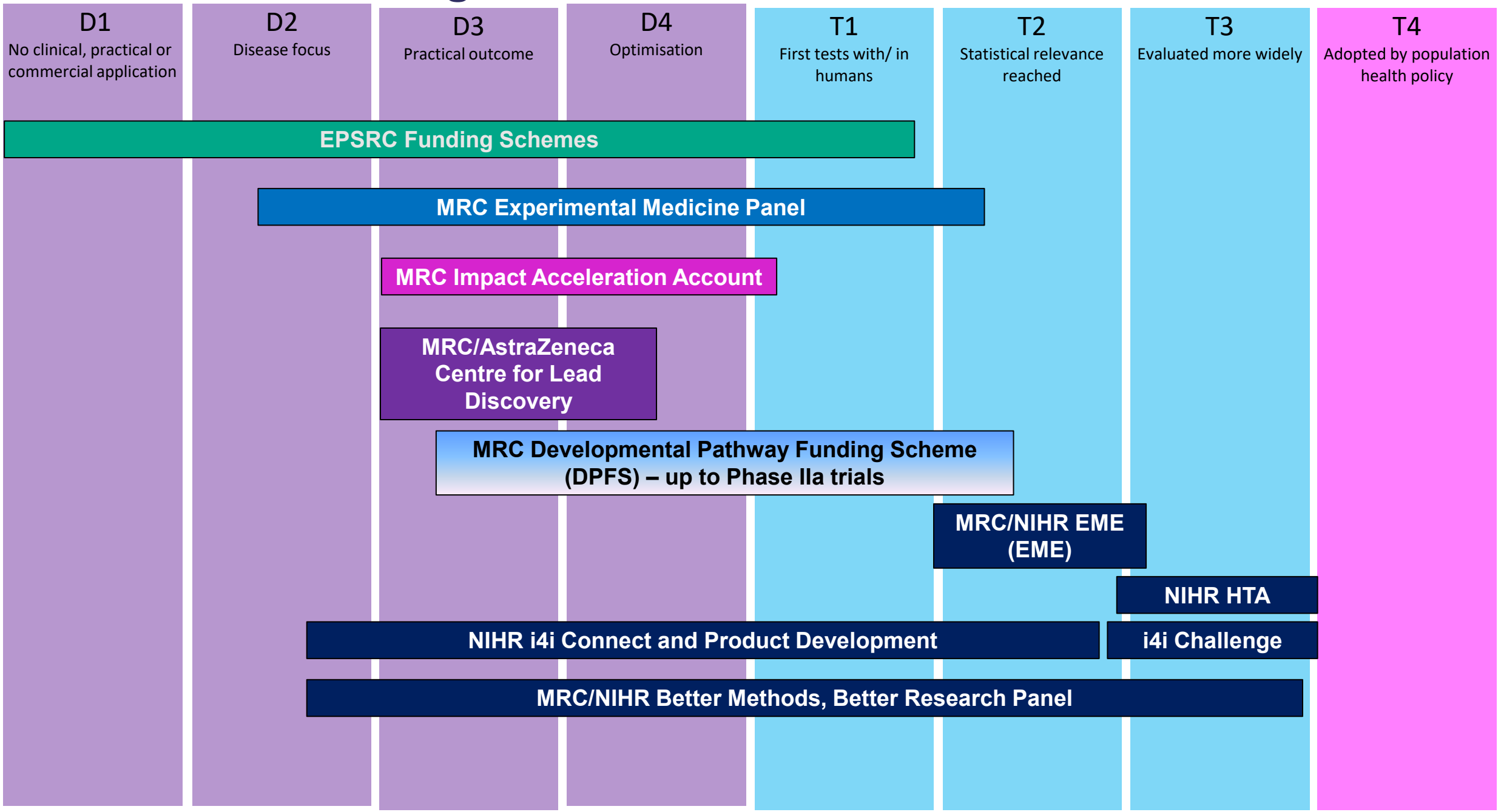
Translational funding schemes



Our approach to translation

- **focusing on the highest priority healthcare challenges** and the research capabilities that will address them
- **partnerships with other funders** to encourage translational research and open up pathways to impact
- **providing support for environments** that promote multidisciplinary research and training
- **stimulating creative and transformational approaches** to address unmet clinical needs and improve patient outcomes
- **maximising business, charity and clinical engagement** in research, thereby increasing translation to products and practices

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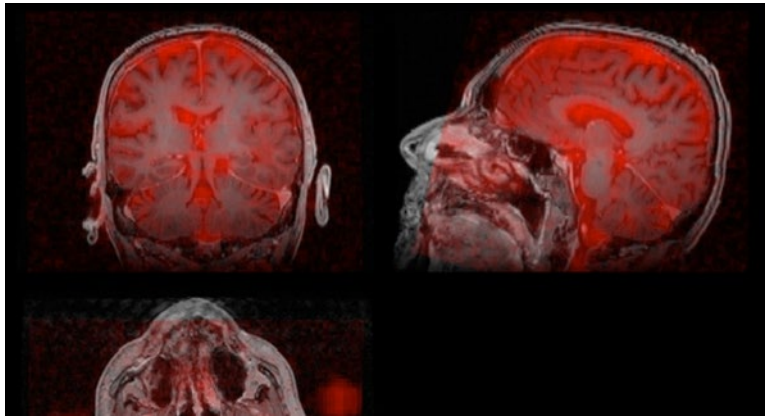
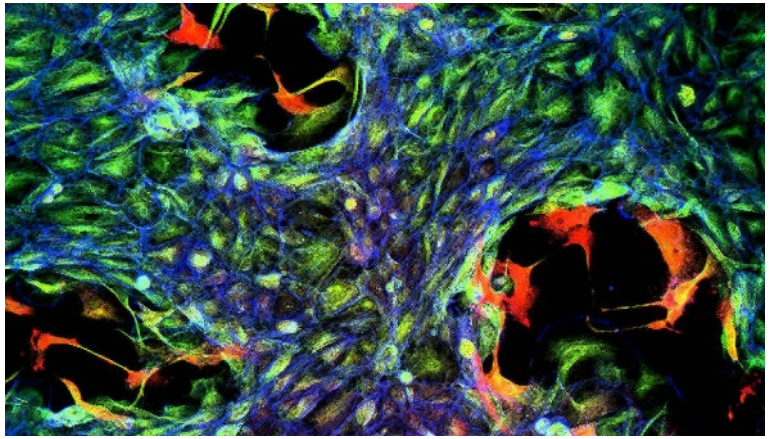
Partnerships- CRUK



Joint cancer imaging centres established in 2008 and renewed in 2013 (£75M total)

CATCHING CANCER EARLIER

Series of innovation sandpits in Early Detection, starting in 2018, bringing together diverse communities to tackle the most difficult early detection problems



Joint support for Multidisciplinary Projects Award Scheme from 2015 (£25M minimum) allowing CRUK to "reach out to EPS and attract new types of thinking into cancer research"

"We weren't really talking to the physical sciences and engineering communities before. We didn't really know how to talk to them, we didn't talk their language and that's what EPSRC has brought"

Ian Foulkes, Executive Director, Strategy and Research Funding at CRUK

UKRI Engineering and Physical Sciences Research Council

Partnerships- Wellcome

Two joint Centres funded in 2016 (£26m)

- Wellcome / EPSRC Centre for Medical Engineering (King's College London)
- Wellcome / EPSRC Centre for Interventional and Surgical Sciences (University College London)

Three joint research projects (£30m)

- iFIND (King's College London): intelligent Fetal Imaging and Diagnosis
- CANDO (Newcastle University): Working towards a first-in-human trial in patients with focal epilepsy
- Gift- Surg (Kings College London): Guided Instrumentation for Fetal Therapy and Surgery

Partnerships- Asthma UK

Asthma UK, NIHR and the British Lung Foundation

- 2020 launched a call for proposals in development of technologies for diagnosis, monitoring and management tools for asthma.
- Successful applicants expected to work in collaboration with representatives from NIHR towards the end of the grant to ensure that they are prepared to apply to one of the i4i calls in order to advance the technology developed.

Engineering and Physical Sciences Research Council

Past Opportunities

Sandpit on digital technologies for health and care

- The concept of the sandpit is an interactive workshop on a topic, involving 25-30 participants.
- This sandpit brought together social scientists, designers, engineers, physical scientists, computer scientists, healthcare professionals, biological scientists and innovators to address the research challenges associated with developing novel digital technologies for improved self-monitoring and health management.

HIPs- Healthcare Impact Partnerships

- The Healthcare Impact Partnership call was launched to enable researchers to progress previously funded EPSRC research towards impact in Healthcare.
- Evaluation: Overall, the HIP scheme has been successful in engaging engineering and physical sciences researchers and facilitating cross sectoral collaboration with industry and clinical stakeholders for the purpose of applying EPS research to healthcare. Technologies have progressed along the translational pathway and desired outputs and outcomes have emerged.

UKRI Engineering and Physical Sciences Research Council

Evaluation of EPSRC's Healthcare Impact Partnerships investment – UKRI

Systems Engineering Innovation hubs for Multiple long-term Conditions (SEISMIC)

- Working in partnership with NIHR
- Initial funding for a development phase followed by more substantial funding
- Proposals invited from multi-disciplinary teams to take a systems design and engineering approach to improve services for people with multiple long-term conditions (MLTC) and their carers.
- Example challenges in scope:
  - Facilitating coordinated care
  - New approaches to shared decision making
  - Bringing together physical and mental health services
  - Providing care at the most convenient locations and times for people with MLTC and their carers
  - Improving the effectiveness/efficiency of the system for the diagnosis, treatment, and ongoing management for people with MLTC or complex care needs
- Call Closes (development stage) – 15 February 2023

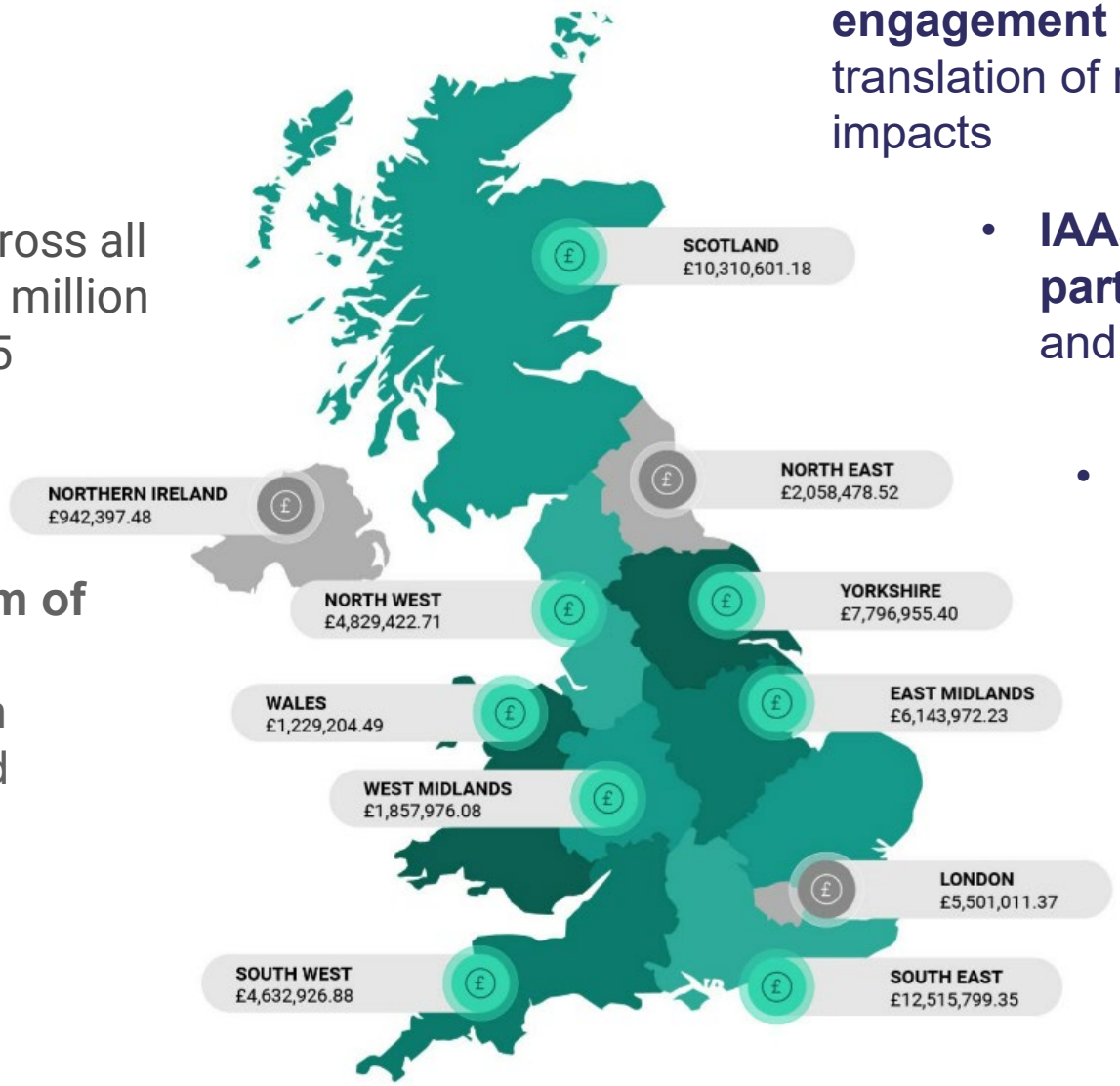
UKRI Engineering and Physical Sciences Research Council

https://www.nihr.ac.uk/funding/22145-systems-engineering-innovation-hubs-for-multiple-long-term-conditions-seismic-development-phase/31866

Impact Acceleration Accounts

IAA funds are distributed between 36 institutions across all regions of the UK, with £60 million committed for 2022 – 2025

EPSRC IAAs take the form of block grants based on competitively-won research portfolios that are managed locally by institutions.



- **IAAs are strengthening user engagement** to accelerate the translation of research outputs into impacts
- **IAAs are developing strategic partnerships** across disciplines and sectors.
- **IAAs help commercialise research outputs** to progress them towards the next stages in the impact pipeline
- **IAAs are building capabilities** within institutions to nurture an impact culture

UKRI Engineering and Physical Sciences Research Council

Proposal Writing Guidance

- Consider your audience: EPSRC PMs, Peer Reviewers, Panel Members – a mix of non-experts, experts and generalists
- Quality is the primary criterion
- Describe novelty and added value
- Be clear about the ideas, methodology and work plan
- Pitch an appropriate and realistic degree of ambition
- Try to avoid jargon

The online guidance is the best starting point:
https://www.epsrc.ac.uk/funding/howtoapply/preparing/writing/

UKRI Engineering and Physical Sciences Research Council

How to check if EPSRC is right for you

- Get advice from established colleagues
- View our research areas and portfolio themes to see if your research matches our structure
- Contact the Portfolio Manager for the area closest to your proposed research
- Search our portfolio of funded grants (https://gow.epsrc.ukri.org/) to see if EPSRC has funded any related projects in similar research areas

Engineering and Physical Sciences Research Council

Final tips

- When applying for a grant read the guidance on the EPSRC website
- Remember the basics: What, How and Why
- Use the space wisely, articulate the methodology clearly
- Look at the reviewer assessment criteria online
- PI response –
  - Read reviewer comments carefully and provide a balanced response
  - Be specific and respond to all of the issues raised
  - Provide evidence for your rebuttal
  - Write your response to the panel members

Your response could be significant during the panel process

Engineering and Physical Sciences Research Council

EPSRC Healthcare Technologies Team

Philippa Hemmings
Theme lead
(Overall strategy, budget)

Andrew Eustace
Senior Portfolio Manager
(Regenerative therapies, CRUK)

Katherine Freeman
Senior Portfolio Manager
(Digital Health, Wellcome, NIHR)

Laura Cadman
Senior Portfolio Manager
(PPIE, Programme Grants)

John Baddeley
Portfolio Manager
(Assistive Technologies,

Kate Reading
Portfolio Manager
(Medical Imaging, Maths/ Engineering, Mental Health)

Zuzana Hlaskova
Portfolio Manager
(Digital Health,)

Cheryl Norcross, Lydia Dunmore, Alison Dunn
Support Team

Firstname.lastname@epsrc.urki.org; healthcare@epsrc.ukri.org;
https://epsrc.ukri.org/funding/applicationprocess/basics/remit/remitqueries/

Engineering and Physical Sciences Research Council

Engineering and
Physical Sciences
Research Council

Questions?

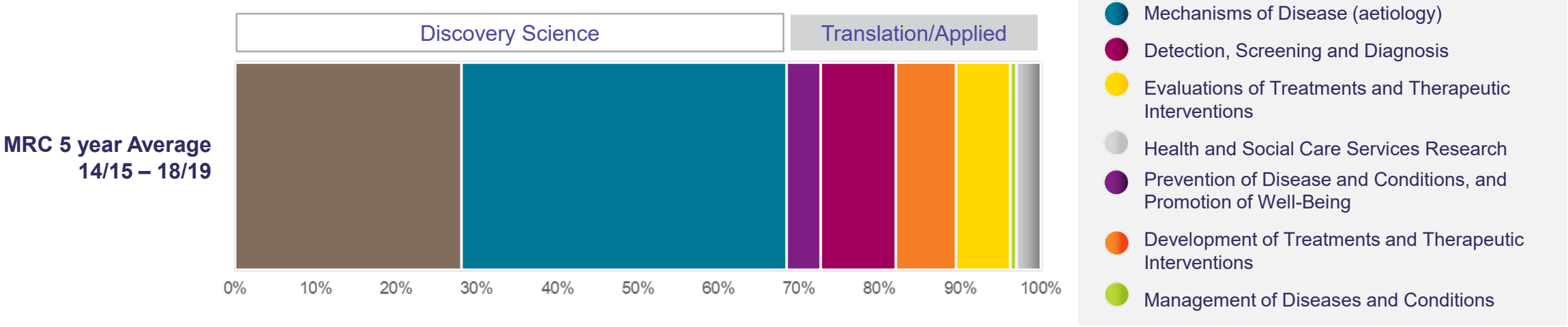
Medical Research Council

MRC Translational Research Funding

Dr Sophie Liddell
MRC Translation Programme Manager

Translational Research at Manchester
16th November 2022

MRC discovery science and applied research portfolio

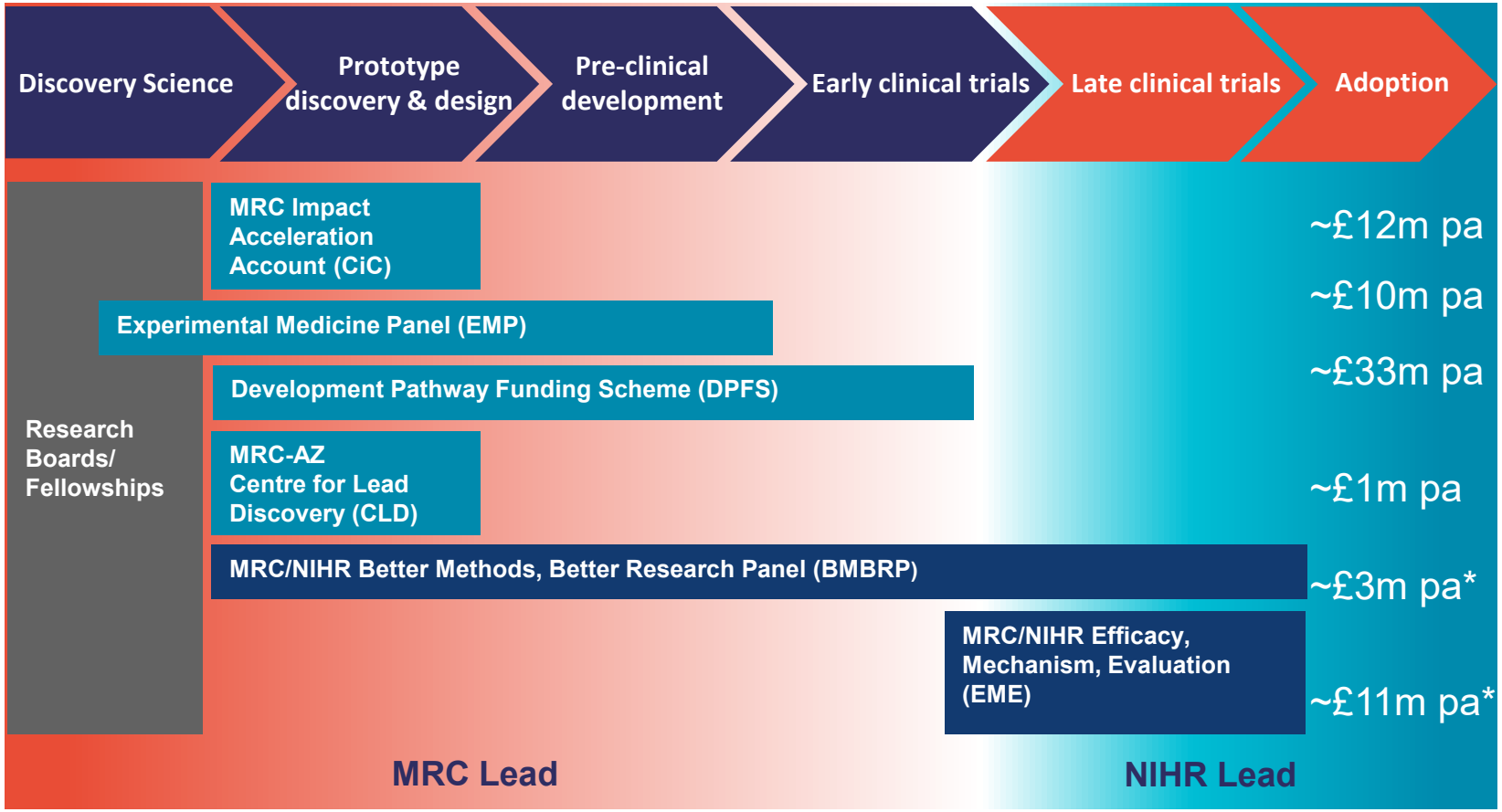


- Strong discovery science and talented, flexible researchers underpin everything
- Creative and reciprocal co-operation with industry
  - Partnerships to tackle complex fields
  - Project by project collaborations across all MRC funding schemes
- Partnerships with Universities, charities, Research Councils, Innovate UK and NIHR

UKRI Medical Research Council

MRC Translational funding schemes

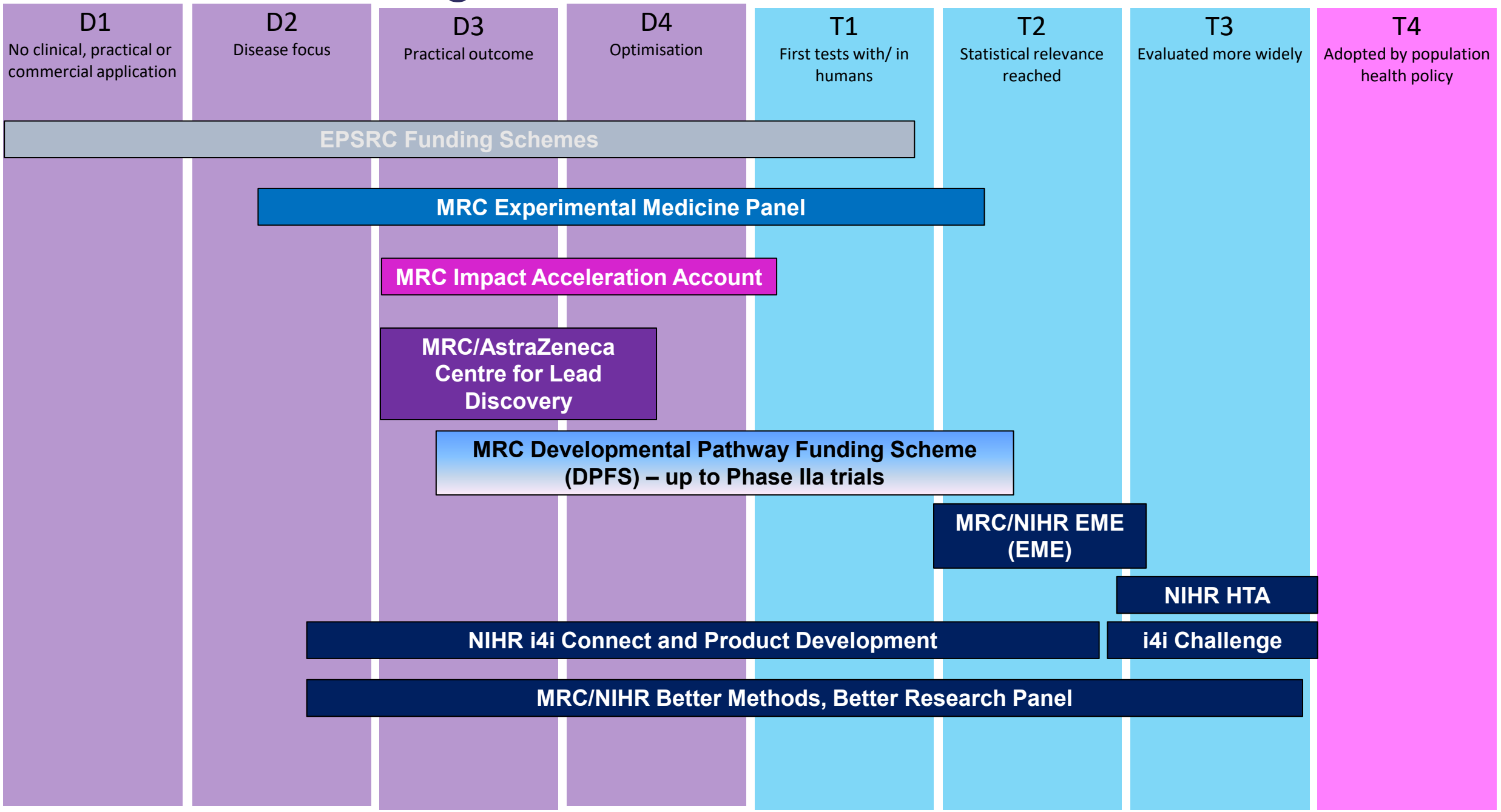
MRC supports studies across clinical and translational medicine, with an annual budget of >£70m



*MRC Contribution

Medical Research Council

Translational funding schemes



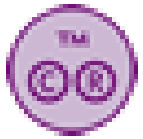
MRC Impact Acceleration Account (IAA)

- Previously known as **Confidence in Concept (CiC)**
- Funding scheme to promote the development of a translational culture within a university
- Awards provided directly to the university to support tightly defined projects designed to create proof of concept data
- Award duration has now increased to 3 years with single application for all Research Council IAAs
- Equivalent to seed funding – infrastructure and a pipeline of projects should already be in place

Since 2013 this scheme has achieved:

Support for **1533** projects with **1699** interactions with industry on projects

>£930M of follow on funding secured



191 patents awarded

81 spin-out companies created

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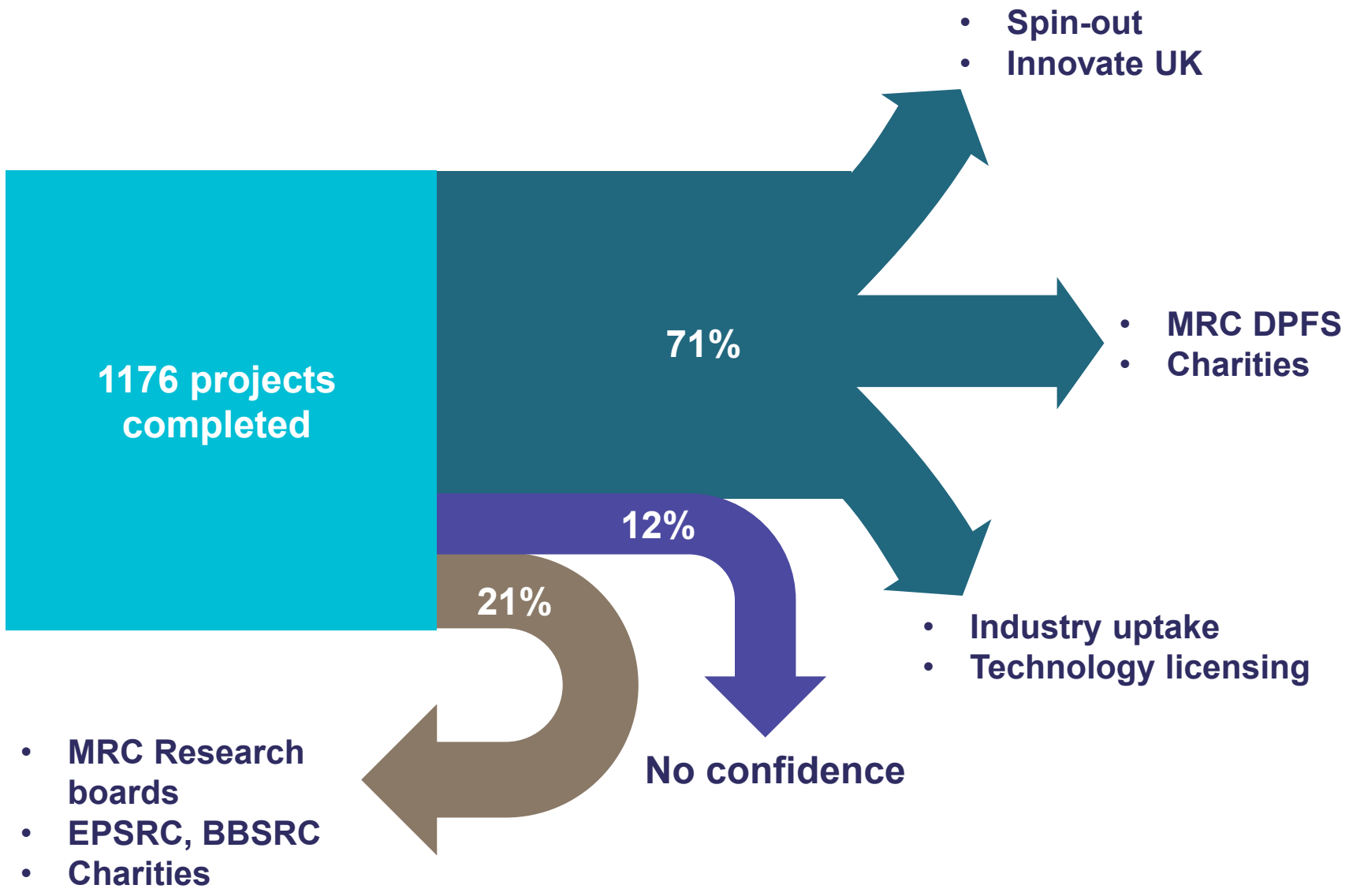
CiC project follow-on funding pathways



Medical Research Council

Developmental Pathway Funding Scheme (DPFS)

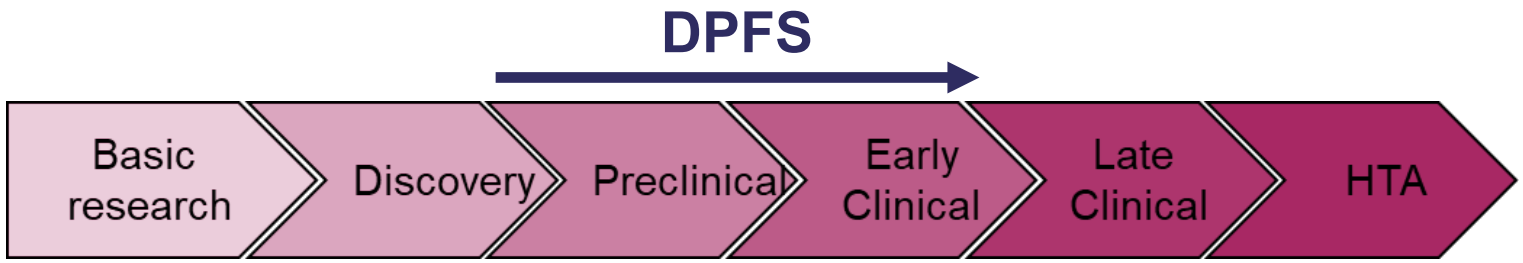
- The **cornerstone** of the MRC's Translational Strategy:
  - To progress academic-led research down the translational pathway
  - ~£30m/year, deadline every four months (March, July, November)
  - No restrictions on duration or value
- **Not just 'Translational Research Grants'**
  - Projects are goal oriented and milestone-based
  - Allows MRC to provide a long-term commitment to inherently risky projects
  - Follow on projects encouraged

UKRI Medical Research Council

Developmental Pathway Funding Scheme (DPFS)

In remit:

- **Development and pre-clinical testing** of **novel** therapeutic entities, devices, diagnostics, imaging technologies and other interventions through to **early-phase clinical studies (Ph I to Ph IIa)**
- "**Repurposing**" clinical studies – existing therapies in new indications
- Development of **research tools that increase the efficiency of developing interventions**
- Interventions of benefit to the health of **low-/middle-income countries**, as well as those of benefit in the **UK**



Out of remit:

- Discovery science including mechanistic studies and biomarker identification (may be more suitable for MRC research boards, Experimental Medicine)
- Technology development where not aligned to a medical/clinical developmental plan (likely BBSRC or EPSRC remit)
- Phase IIb and III clinical trials & trials of non-novel agent-disease combinations (NIHR)
- Later stage development, trials and implementation studies for global health (MRC Applied Global Health Research Board)

UKRI Medical Research Council

DPFS Awards

As of May 2021, **296** projects have been supported through the DPFS, ranging from pre-clinical studies to Phase II clinical trials, with a total commitment of more than **£350m**.

No restrictions on disease or modality – all about clinical need.

Therapeutic intervention include:

- 49 small molecule
- 47 biologics (antibodies, proteins etc.)
- 14 drug ‘other’
- 27 genetic therapies
- 14 cell therapies
- 18 medical devices
- 7 psychological interventions
- 25 vaccines
- 47 diagnostics
- 17 others

Experimental Medicine Panel

Applications must involve experimental **intervention/challenge** in **humans** - perturbing the system to explore disease mechanism

Studies should be centred around a strong **mechanistic hypothesis**

Studies should be powered for **mechanism** not efficacy

- £10 million annual budget to support a range of award sizes and durations
- Two stages (Outline + Invited Full applications) - Two Outline deadlines per year (March/Sept)
- Flexibility on PI eligibility. Open to early career investigators without a contract of employment with the RO for the duration of the grant
- All disease areas and interventions are welcome
- Partnerships with industry and charities encouraged but not a pre-requisite

UKRI Medical Research Council

DPFS and Experimental Medicine – application tips

DO

- ✓ Speak to an MRC programme manager before developing your application
- ✓ Assemble a team including all the necessary/relevant expertise: clinicians, technical experts, statisticians, project management, end-users etc.
- ✓ For DPFS, clearly state the clinical need and show how your solution will meet that need
- ✓ Design meaningful, SMART milestones that will de-risk project progression
- ✓ Read all the guidance and use other resources available – including local expertise
- ✓ Carefully consider where your project fits on the pathway to patients, and what comes next
- ✓ Consider partnerships and opportunities for commercialisation, but don't worry if "there is no IP" or you don't have a partner for the project
- ✓ Understand the assessment process and timeline (2 stages; can delay full application if invited; peer review at full application stage; no PI response stage for DPFS)

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DPFS and Experimental Medicine – application tips

DON'T

- ✗ Under-cost or over-stretch – there are no limits on size/duration of grants so ask for what you need
- ✗ Rush your application – deadlines are three times a year for DPFS, twice a year for Exp Med. But if declined, you have to wait 12 months to reapply
- ✗ Make the Panel work too hard to understand the need, project plan or supporting data. No peer review from specific experts at outline stage so write for your audience – the broadly expert Panels

For DPFS:

- ✗ Believe the myths surrounding DPFS – the scheme has evolved over time
- ✗ Skimp on understanding whether you have freedom-to-operate for the project and future development
- ✗ Dismiss or neglect to mention competing solutions – explain why yours is better

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Industry Collaboration Framework (ICF)

- Replaced the MRC-Industry Collaboration Agreement (MICA) in April 2022
- A framework to support partnership with companies, ensuring that all rights and responsibilities are laid out at the start of a project
- New process is more streamlined, with clearer guidance
- Many industry partnerships don't need to be considered under the ICF; the decision tree will help you to work out the types of relationship and arrangements that do.

Tips:

- ✓ **Speak to Translation Manchester and/or MRC to clarify things early**
- ✓ **Don't be put off - it's there to help you**
- ✓ **Industry partnership is absolutely not a pre-requisite for a successful application – the wrong partnership can be much worse than none at all!**

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https://www.ukri.org/councils/mrc/guidance-for-applicants/types-of-funding-we-offer/mrc-industry-collaboration-framework-icf/

Do you need small molecule starting points for your therapeutic target?

Medical Research Council

AstraZeneca

The MRC & AstraZeneca Centre for Lead Discovery

Active chemical substances (drugs), account for ~90% of the medicines available today

High-Throughput Screening (HTS) is an efficient way of identifying new small molecule start points

Early Structure Activity Relationships (SAR) can lead to hit expansion and lead optimisation medicinal chemistry programmes

Delivering academics small molecule chemical hits

Are you an academic researcher interested in drug discovery ?

With an idea for a future therapeutic candidate ?

Do you have a clear line-of-sight to the clinic ?

Projects can be against targets of your choice!

Outputs ready for initiation of hit-2-lead medicinal chemistry

Providing academics unique access to AZ's collection of over 2 million compounds & state-of-the-art HTS robotics (NiCoLA-B)

What assays do I need?

Minimum requirements include:

- Minimum of 3 independent 96 well plate assay runs
- Assay that is amenable to be miniaturised to 384/1536 well
- Signal to Background ratio ideally >3
- %CV max activity/DMSO Vehicle plates ideally <10%
- Robust Z' ideally >0.5
- Small scale protein production and/or cell culture achieved
- Stable reagents – Both on bench and assay stability

How will I benefit from this initiative?

You will receive

- Data and structures on up to 3 Hit Series with up to 15 exemplar chemical structures
- Future freedom to operate – Beyond initial first right to negotiate option to AZ
- MRC Developmental Pathway Funding Scheme can be used for future Hit-2-Lead optimisation programmes

Funding Opportunity: Develop new approaches to small molecule medicine – UKRI

mrc.ukri.org/blog
twitter.com/The_MRC
youtube.com/mrccomms
linkedin.com/company/medical-research-council
mrc.ukri.org/podcast
facebook.com/mrccomms
Scoop.it/mrc-news

For more details or to discuss an application please email:
highthroughputscreen@mrc.ukri.org

MRC and AstraZeneca Centre for Lead Discovery

Rolling deadline funding opportunity:

https://www.ukri.org/opportunity/develop-new-approaches-to-small-molecule-medicine/

Contact details

If you have any questions regarding MRC Translational funding opportunities, please contact **DPFSandDCS@mrc.ukri.org** or one of the Translation Programme Managers:

Dr Adam Babbs (Adam.Babbs@mrc.ukri.org)
Small molecules and drug (other)
MRC/AZ Centre for Lead Discovery

Dr Tim Ellis (Tim.Ellis@mrc.ukri.org)
Biomarkers and diagnostic, psychological therapies

Dr Agnes Leong (Agnes.Leong@mrc.ukri.org)
Medical and Therapeutic devices
MRC IAAs (CiC)

Dr Sophie Liddell (Sophie.Liddell@mrc.ukri.org)
Drug & Small Molecule repurposing studies

Dr Penny Morton (Penny.Morton@mrc.ukri.org)
Advanced therapeutics: vectors, gene, nucleic acid and siRNA therapies

Dr Alex Phillips (Alexandra.Phillips@mrc.ukri.org)
Vaccines, antibodies, proteins and peptide therapeutics
Experimental Medicine Panel

Dr Suzanne Rix (Suzanne.Rix@mrc.ukri.org)
Digital health (software development/AI tools) and imaging, Regenerative Medicine

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Other resources

- The **MRC Regulatory Support Centre** provides support and guidance for those conducting research with human participants, their tissues or data.
- The National Institute for Health Research provides a **clinical trials toolkit** that gives practical advice to those planning or running clinical trials in the UK.
- The **MHRA Innovation Office** provides free advice to clarify regulatory requirements from an early stage of product development.
- Applicants considering a drug repurposing project may wish to explore the **Repurposing Medicines Toolkit**, recently developed by MRC and LifeArc.
- The **MRC-LifeArc Innovation Hubs for Gene Therapies Network** supports academic-led early phase clinical development of gene therapies through manufacturing of GMP viral vector, translational and regulatory support, and manufacturing development support ahead of clinical development.
- The **Nucleic Acid Therapy Accelerator (NATA)** provides dedicated research capability, infrastructure and support to enable advances in the development of nucleic acid therapeutics.

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Thank you

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NIHR | National Institute for Health and Care Research

National Institute for Health and Care Research

MRC-NIHR Efficacy and Mechanisms Evaluation (EME) Programme

Dr Juliana Callaghan

Acting Head of EME Programme

Topics we will cover today

- The NIHR and its Research Programmes
- The translational research funding landscape
- What will EME fund?
- What won’t EME fund?
- The application/funding process
- Hints and Tips

NIHR funds, enables and delivers world-leading health and social care research

We fund or part-fund over 10,000 front-line research delivery staff throughout the NHS

We're funding more than 1,000 active health and social care research projects

More than 2,000 researchers hold our career development awards

More than a million participants take part in research supported by the NIHR each year

NIHR's mission is to improve the health and wealth of the nation through research.

Funding high quality, timely research that benefits the National Health Service, public health and social care

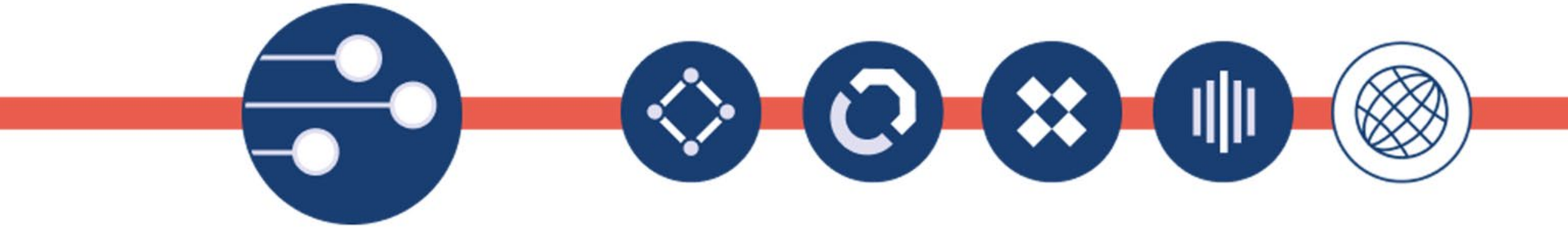
Investing in world class expertise, facilities and a skilled delivery workforce to translate discoveries into improved treatments and services

Partnering with patients, service users, carers and communities improving the relevance, quality and impact of our research

Attracting, training and supporting the best researchers to tackle complex health and social care challenges

Collaborating with other public funders, charities and industry to shape a cohesive and globally competitive research system

Funding applied global health research and training to meet the needs of the poorest people in low and middle income countries



Funding high quality, timely research

that benefits the NHS, public health and social care

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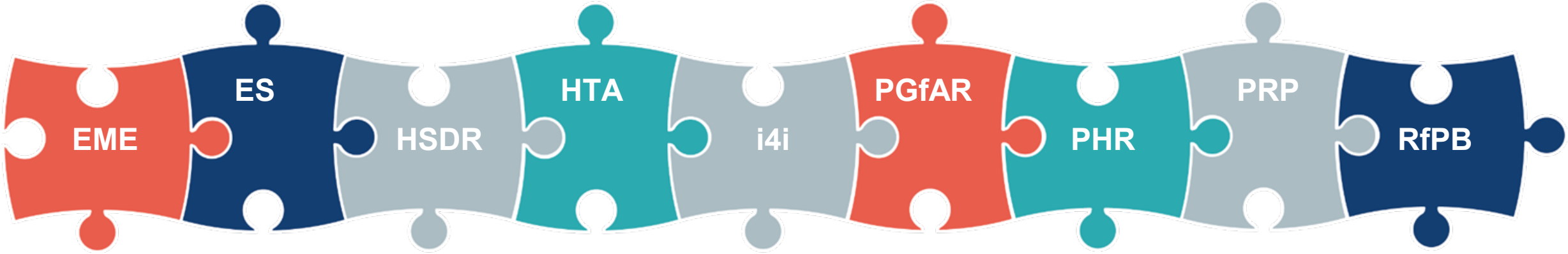
Our research programmes



We have nine research programmes that fund multi-disciplinary health and social care research in both clinical and non-clinical settings to meet a range of evidence priorities, including:

- Clinical evaluation and translation
- Health services and organisation
- Technology development
- Public health
- Social care

https://www.nihr.ac.uk/researchers/apply-for-funding/how-to-apply-for-project-funding/our-funding-programmes.htm

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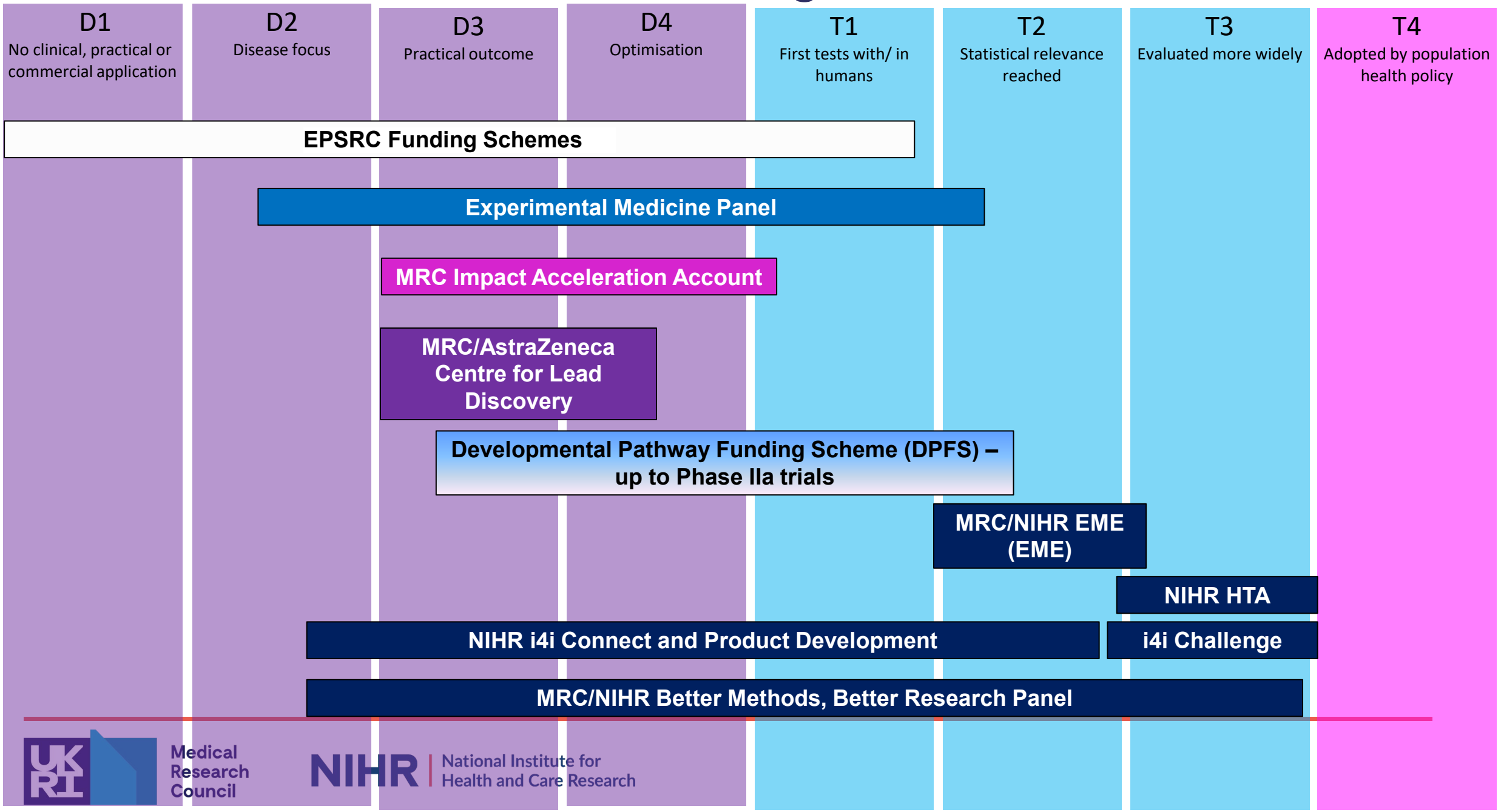
The translational research funding landscape

UKRI –EPSRC / MRC & NIHR Funding Schemes



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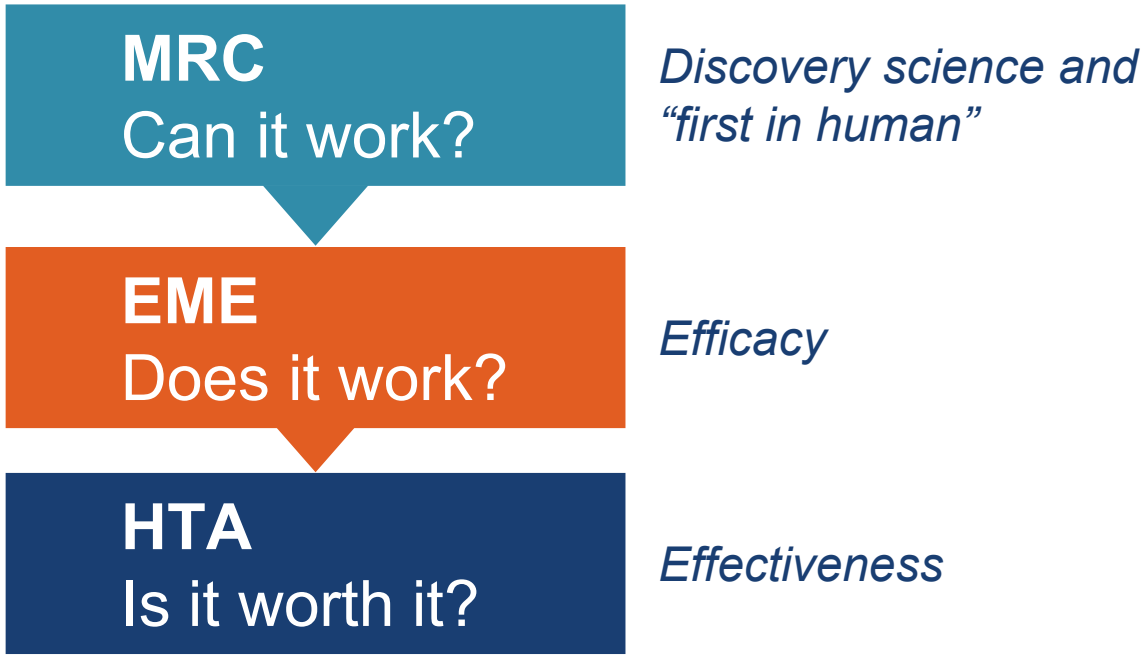
Funding landscape

In simple terms:



EME
Does it work……
And how?

EME studies take one of three forms:

- **Efficacy study** - to evaluate the efficacy of an intervention for which there is 'proof of concept' in humans;
- **Mechanistic study** - to test hypotheses around mechanism of action of an intervention
- **Combined Efficacy and Mechanistic study** – to evaluate the efficacy of an intervention and test hypotheses for its mechanism of action, within the same study.

HTA
Is it worth it?

- Studies should evaluate the **clinical and cost-effectiveness** of a therapeutic intervention or diagnostic test, measured with outcomes that are important to patients.
- Research is typically undertaken when evidence exists to show that a technology can be effective and this needs to be compared to the current standard intervention.

https://www.nihr.ac.uk/explore-nihr/funding-programmes/health-technology-assessment.htm

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What will EME fund?

What will EME fund?

- Research to determine proof of clinical efficacy, size of effect, and safety in a well-defined population.
- The evaluation of a broad range of interventions which have the potential to maintain health, treat disease or improve recovery.
- Hypothesis-driven research based on an efficacy study, to explore the mechanisms of action of interventions, causes of differing responses or disease mechanisms.
- Studies using novel or infrequently-used study designs which increase the value of a study, by maximising the chances of demonstrating the benefit of an intervention, or increasing the knowledge that can be gained.

What will EME fund?

Ways to support translation or ‘pull-through’ of research

- Embedded pilot and feasibility studies where the main study would be within the remit of the EME programme.
- The final development of an intervention prior to proceeding to the main clinical evaluation within the same application.
- Proposals that include a series of linked stages with progression to the main clinical evaluation dependent on the outcome of the previous stage(s).

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What won’t EME fund?

What won’t EME fund?

- Large effectiveness studies that test the impact of the introduction of an intervention in the wider NHS.
- Hypothesis-generating studies, e.g. biomarker discovery.
- Confirmatory studies or minor modifications.
- Research into areas where the health need is identified primarily outside the UK.
- Any research involving animals or animal tissues.

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The funding application and review process

Two work streams: Commissioned and Researcher-led

Researcher-Led

Open calls for researchers to apply for funding for their own topics and questions, within the remit of the relevant programme

Commissioned

Calls for research in a specific area. Designed to meet the needs of decision makers within the NHS & social care settings.

https://www.nihr.ac.uk/researchers/funding-opportunities/

The Application and Funding Process

Stage 1 Application Process

Stage 1 application

Pre-filter (Remit & competitiveness panel)

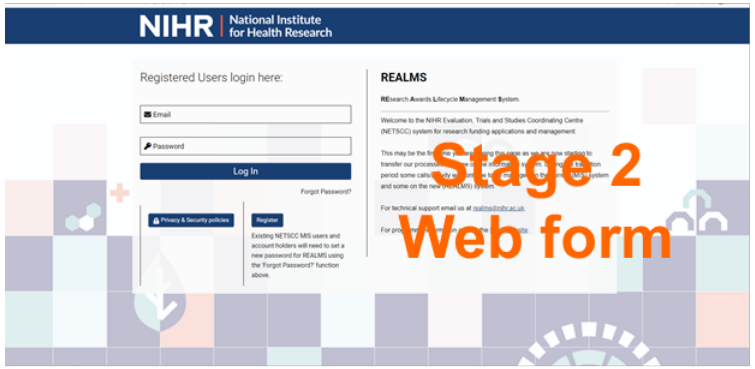
Designated Committee Members (DCMs) selected

Funding Committee meeting

Outcome letter

The Application and Funding Process

Stage 2 application process



Stage 2 application

Reviewer(s)

Applicant responds to reviewer(s)

Designated Committee Members (DCMs) usually retained from stage 1

Funding Committee meeting

Final outcome letter

Contract <9 months

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Hints and Tips

Hints and Tips

Ask us for advice EME@NIHR.ac.uk

- Please send in a **PICO** summary.
  - **Patients/Population** – who/what
  - **Intervention** – how
  - **Comparator** – placebo/treatment as usual etc
  - **Outcome** – this should be a patient-centred effect

    For work relating to mechanism of action of an intervention, please describe any hypothesis being tested
- Proof of concept
  - Please cite any evidence that the intervention could work. How much evidence is needed will vary depending on the size of the translational step, the scale of the study and the nature of the intervention. Please see this webpage for more details

Hints and Tips

Research Question

- Describe unmet health need being addressed in the context of current practice and provide the size of the incident or prevalent patient population in the UK
- Ensure the question has not already been answered: look at our online portfolio, and other funders
- PPI work is required to ensure it is relevant to patients/the public and please also ensure the plain English summary is clear
- Is it timely and will it make a difference?
- Can it be delivered by the NHS/Social Care?
- Ensure all hypotheses being tested for the clinical study and any mechanistic work are clearly defined including how you will confirm or refute them. NB. Applications must be hypothesis-driven, i.e. funding will not be available for studies where the main aim is hypothesis generation.

Hints and Tips

Study Design

- Ensure the design is optimised to answer the question
- Choose the most robust research method and fully describe it clearly
- Describe the planned inclusion/exclusion/withdrawal criteria, how participants will be allocated to trial groups and any methods to protect against bias
- Describe and justify the choice of primary outcome, and any secondary outcomes
- Explain the dose and any side effects of the intervention
- Include a statistical analysis plan and ensure the sample size/power calculation be replicated
- Use existing support, e.g. Research Design Service (RDS), CTU

Hints and Tips

Research Team

- Do your team have the multi-disciplinary expertise you need?
- Ensure the roles are clearly defined and appropriate
- Consider the level and range of expertise required; use your CTUs
- Ensure that PPI is demonstrated at all stages
- We would usually expect at least two of the following organisation types to be involved: NHS, academia and industry

Hints and Tips

Deliverability

- Recruitment: have you made a convincing case that your recruitment plan is realistic and addressed any EDI issues
- Is your timeline manageable?
- Does your application provide value for money, and are the costs correctly allocated? See the AcoRD guidance for how to allocate treatment costs:

  https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

Hints and Tips

Dissemination and Impact

- Describe the deliverables of the project
- Is there a clear pathway to dissemination and impact?
- What are the next steps involved after the project has completed?
- How will the research impact current practice?
- Are there any barriers for further research, development, adoption and implementation

Hints and Tips

Feedback

- Provide a robust response to any feedback from:
    - External Reviewers
    - Funding Committee Members
- Clearly describe any changes made
- If you disagree with any feedback, explain your justification

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Thank you

Contact us

eme@nihr.ac.uk

Useful resources

https://www.nihr.ac.uk/explore-nihr/funding-programmes/efficacy-and-mechanism-evaluation.htm

Translational Research Manchester 2022

Progress your translational research with the support of our network

Scan to complete the translational bottlenecks and event feedback survey

@Translation_Mcr

#TranslationMCR22

MANCHESTER 1824
The University of Manchester

wellcome