# NIHR FUNDING PROGRAMME INFORMATION EVENT

## 24 OCTOBER 2022

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# AGENDA

| | |
|---|---|
| Anna Dominiczak | Welcome from the Chief Scientist |
| Alan McNair | NETSCC schemes – CSO funding |
| Julie Simpson | Scotland success rates |
| Lisa Douet | The available NETSCC schemes |
| Andrew Horne | NETSCC Grant Holder |
| Rebecca Reynolds | HTA  Panel Member |
| Vittal Katikireddi | PHR Panel Member |
| John Petrie | EME Panel Member |
| Stephen Turner | NETSCC Grant holder |

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# PROFESSOR DAME ANNA DOMINICZAK

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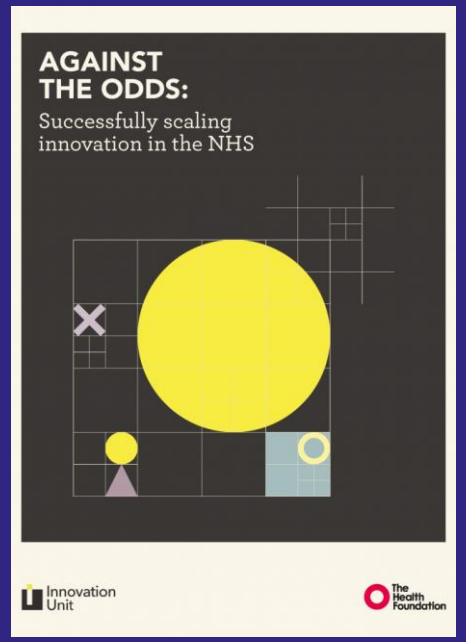


# THE OPPORTUNITY

**“There is broad agreement that the pressures and challenges currently facing health and social care can only be addressed if outcome-improving, experience-enhancing and value-adding innovations can be rapidly identified and adopted”**

**“Radical, perhaps even disruptive, innovation at scale has become a necessity, not a luxury”**


# THE CHALLENGE

**“Health and social care in Scotland currently has a rich but uncoordinated landscape for innovation, with many players. Some are duplicating others and some are pulled in at the wrong point of the innovation pathway, which can slow down momentum.”**

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# RESEARCH AND DEVELOPMENT

## Three Regional Test Beds


£3.5 million invested over 2022/23

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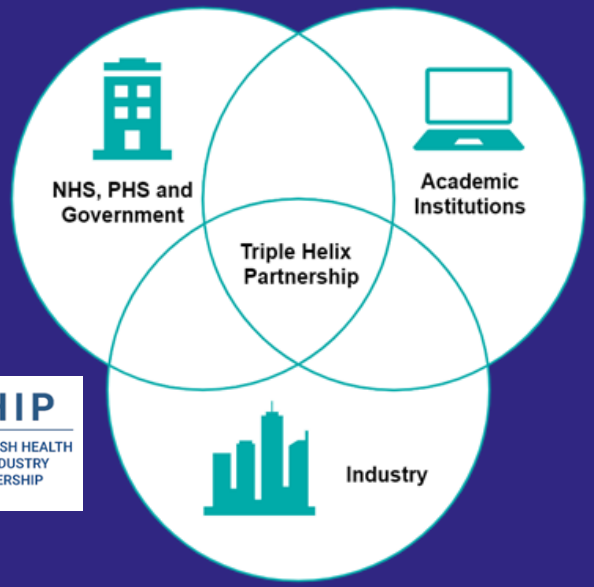
## Triple HELIX




SHIP
SCOTTISH HEALTH AND INDUSTRY PARTNERSHIP

## Industry Partnership Group

abbvie
AMGEN
AstraZeneca
Bristol-Myers Squibb
CHILTERN
Daiichi-Sankyo
gsk
IQVIA
janssen
PHARMACEUTICAL COMPANIES OF Johnson & Johnson
labcorp
LumiraDx
MEDPACE
NOVARTIS
Pfizer
abpi
PPD
Roche

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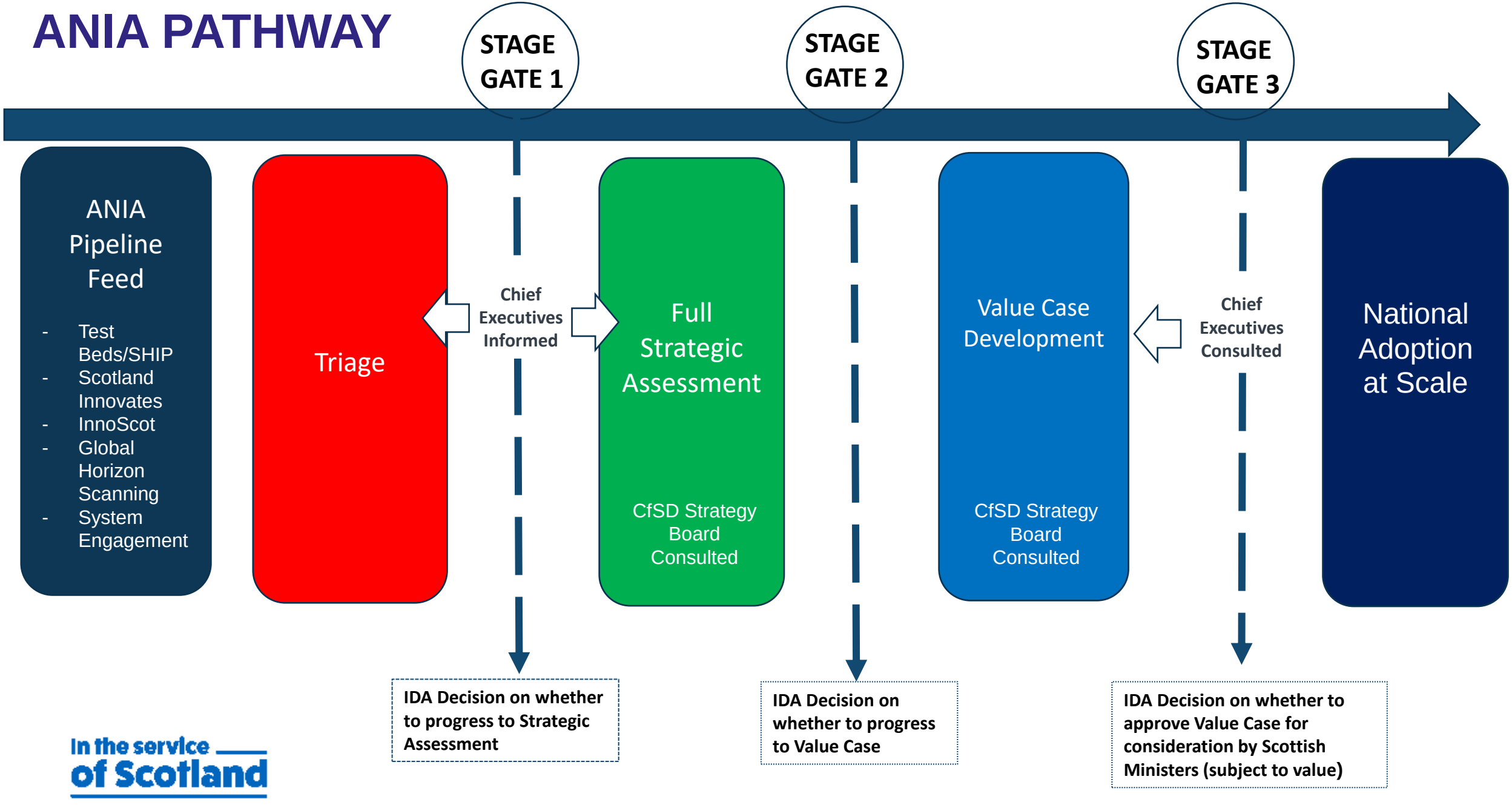
# ANIA PATHWAY

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# Chief Scientist Office

- **CHIEF SCIENTIST OFFICE**
  - Part of Scottish Government Health & Social Care Directorates
  - Remit to support and increase the level of high quality Health and Care research conducted in Scotland
  - Around 25 core staff

## CSO BUDGET – 3 KEY THEMES

### DIRECT RESEARCH FUNDING

Project funding through 2 response mode committees; fellowship schemes

### NHS RESEARCH SCOTLAND INFRASTRUCTURE FUNDING

NHS R&D; Research Networks; Biorepositories; Data Safe Havens; CRF's etc.

### CONTRIBUTION TO NIHR PROGRAMMES

NETSCC administered programmes – EME, HS&DR, HTA, PHR

# Research Funding Schemes

**Response Mode Funding Schemes**

**Translational Clinical Studies Research Committee** - for research aimed at improving treatments and / or diagnostic approaches for conditions of clinical importance to the population of Scotland.

**Health Improvement, Protection and Services Research Committee** - for research aimed at improving or protecting population health or improving the quality, safety and/or effectiveness of healthcare in Scotland.

**Fellowship funding**

**CSO Clinical Academic Fellowships** - for clinical professionals early in their career to do a PhD.

**NES/CSO Postdoctoral Clinical Lectureships** - for medical doctors in speciality training who have completed a PhD but wish to spend 50% of their time on research and 50% of time on clinical training.

**Early Postdoctoral Fellowships** - for 3 years of support to health researchers following completion of a PhD.

**NRS Career Researcher Fellowships** - to support NHS-funded clinical staff in developing a research career.

**NHS Scotland Innovation Fellowship Scheme** - to support NHS-funded clinical staff in developing an innovation career.

**Bespoke calls**

**Rapid research in COVID, Long-COVID, Precision Medicine Alliance Scotland**

**Initiatives with other funders**

**Health Data Research UK, UK Prevention Research Partnership, co-funded projects/fellowships with medical research charities**

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# Infrastructure Overview

NHS SCOTLAND
NHS RESEARCH SCOTLAND

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- **NHS Scotland**
  - Health and Care devolved to Scottish Government
  - Covers 5.5m people
  - 160,000 staff
  - Unitary Health Boards cover both Primary and Secondary Care
- **Health Research is coordinated by the CSO, part of the Scottish Government**
  - CSO provides total funding of ~£50m per year to NHS Research Scotland to support and coordinate health research activity
- **NRS works with HRA, NIHR and other UK partners**
  - Operating within the IRAS approvals and costing frameworks

## National Infrastructure

**CENTRAL MANAGEMENT TEAM (NRS-CMT)**

National point of contact

**PERMISSIONS COORDINATING CENTRE**

Coordinated multisite approvals

**NETWORKS & SPECIALTY GROUPS**

26 Networks led by internationally recognised clinical academics

SHARE

300,000 registered interest to be contacted about clinical studies

## Regional Infrastructure

**CLINICAL RESEARCH FACILITIES**

Dedicated clinical **research space** and **expertise** to support delivery of multidisciplinary clinical research.

**BIOREPOSITORIES**

Network of centres providing nationally co-ordinated access to **human tissue samples**

**DATA SAFE HAVENS**

Robust and secure access to **NHS data**

## CSO BUDGET – 3 KEY THEMES

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# AIMS FOR TODAY

- TO PROVIDE A POLICY CONTEXT TO CSO's BUY-IN TO NETSCC SCHEMES
- TO ENSURE AWARENESS OF THE SCHEMES WE BUY INTO
- TO HEAR ABOUT THE REMIT AND APPLICATION PROCESSES FOR THE ABOVE PROGRAMMES
- TO HEAR FROM SUCCESSFUL APPLICANTS
- TO HEAR FROM SCOTTISH-BASED PANEL MEMBERS FOR THE EME, HTA AND PHR SCHEMES

- OVERALL AIM – TO INCREASE THE NUMBER AND QUALITY OF SCOTTISH-LED APPLICATIONS

# HOUSEKEEPING

- Microphones and Camera – Please keep these off
- **Questions** – Use the chat function

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# DR ALAN MCNAIR
## CHIEF SCIENTIST OFFICE

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# Research Funding Schemes

## Response Mode Funding Schemes

**Translational Clinical Studies Research Committee** - for research aimed at improving treatments and / or diagnostic approaches for conditions of clinical importance to the population of Scotland.
https://www.cso.scot.nhs.uk/grant-funding/response-mode-funding-schemes/translational-clinical-studies-research-committee/

**Health Improvement, Protection and Services Research Committee** - for research aimed at improving or protecting population health or improving the quality, safety and/or effectiveness of healthcare in Scotland.
https://www.cso.scot.nhs.uk/grant-funding/response-mode-funding-schemes/health-improvement-protection-and-services-research-committee/

Each committee meets 2x per year – on average 20-25 projects funded across both committees per year
https://www.cso.scot.nhs.uk/funded-research/translational-clinical-studies/
https://www.cso.scot.nhs.uk/funded-research/health-improvement-protection-and-services/

**Funding limit £300K at 80% Full Economic Cost**

**2-Stage application process – overall success rate ~ 25%**

**Time from submitting outline application to final funding decision notification ~ 6 months**
**(2-3 months if unsuccessful at triage)**

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# Impact Report

## Rapid Research in Covid-19 Programme


| Projects | Value | |
|---|---|---|
| 1 | £44,581 | University of the Highlands and Islands Oilthigh na Gàidhealtachd agus nan Eilean |
| 1 | £36,118 | SRUC |
| 10 | £480,707 | University of Stirling |
| 3 | £136,290 | GCU Glasgow Caledonian University |
| 9 | £1,025,458 | University of Glasgow |
| 5 | £649,993 | University of Strathclyde |
| 1 | £128,882 | UWS University of the West of Scotland |

| Projects | Value | |
|---|---|---|
| 6 | £972,870 | University of Aberdeen |
| 1 | £55,789 | Robert Gordon University Aberdeen |
| 2 | £487,710 | University of Dundee |
| 3 | £132,719 | University of St Andrews |
| 3 | £166,826 | Edinburgh Napier University |
| 8 | £602,500 | The University of Edinburgh |
| 2 | £92,424 | Queen Margaret University Edinburgh |
| 1 | £206,300 | IOM |

Over **45** peer reviewed articles

**27** policy engagements

**250+** dissemination activities
press articles, podcasts, videos, blogs and presentations

**£5** million+ in further research grant funding

**2** spin out companies

# NETSCC Schemes

**Efficacy and Mechanism Evaluation**
Researcher-led and Commissioned
https://www.nihr.ac.uk/explore-nihr/funding-programmes/efficacy-and-mechanism-evaluation.htm

**Health and Social Care Delivery Research**
Researcher-led and *Commissioned (as co-applicant only)*
https://www.nihr.ac.uk/explore-nihr/funding-programmes/health-and-social-care-delivery-research.htm

**Health Technology Assessment**
Researcher-led and Commissioned
https://www.nihr.ac.uk/explore-nihr/funding-programmes/health-technology-assessment.htm

**Public Health Research**
Researcher-led and Commissioned
https://www.nihr.ac.uk/explore-nihr/funding-programmes/public-health-research.htm

***Invention for Innovation (i4i)***
***Policy Research Programme***
***Programme Grants for Applied Research / Programme Development Grants***
***Research for Patient Benefit***

# DR JULIE SIMPSON

## CHIEF SCIENTIST OFFICE

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# SCOTTISH SUCCESS RATES

| EME | 17/18 | 18/19 | 19/20 | 20/21 |
|---|---|---|---|---|
| Funded (Scottish) Projects | 0 | 0 | 0 | 2 |
| Total (Scottish) Application | 2 | 7 | 6 | 5 |
| **Success Rate** | **0 %** | **0 %** | **0 %** | **40 %** |
| **HSDR*** | | | | |
| Funded (Scottish) Projects | 0 | 0 | 3 | 2 |
| Total (Scottish) Application | 3 | 5 | 13 | 8 |
| **Success Rate** | **0 %** | **0 %** | **23 %** | **25 %** |
| **HTA** | | | | |
| Funded (Scottish) Projects | 8 | 3 | 13 | 9 |
| Total (Scottish) Application | 30 | 30 | 30 | 26 |
| **Success Rate** | **29.6 %** | **10 %** | **43.3 %** | **34.6 %** |
| **PHR** | | | | |
| Funded (Scottish) Projects | 1 | 2 | 6 | 3 |
| Total (Scottish) Application | 12 | 13 | 15 | 11 |
| **Success Rate** | **8.3 %** | **15.4 %** | **40 %** | **27.3 %** |

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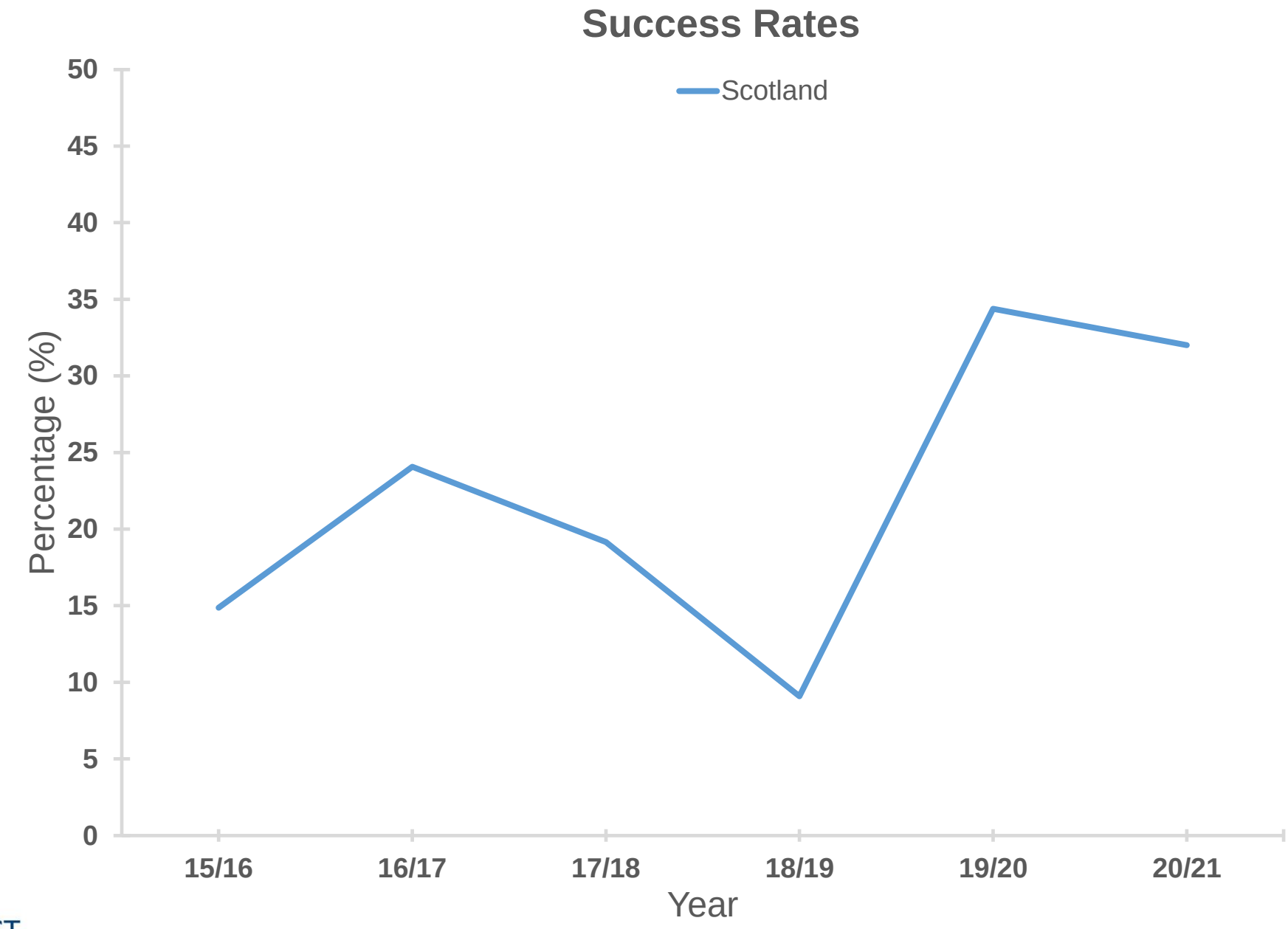
*Research led only

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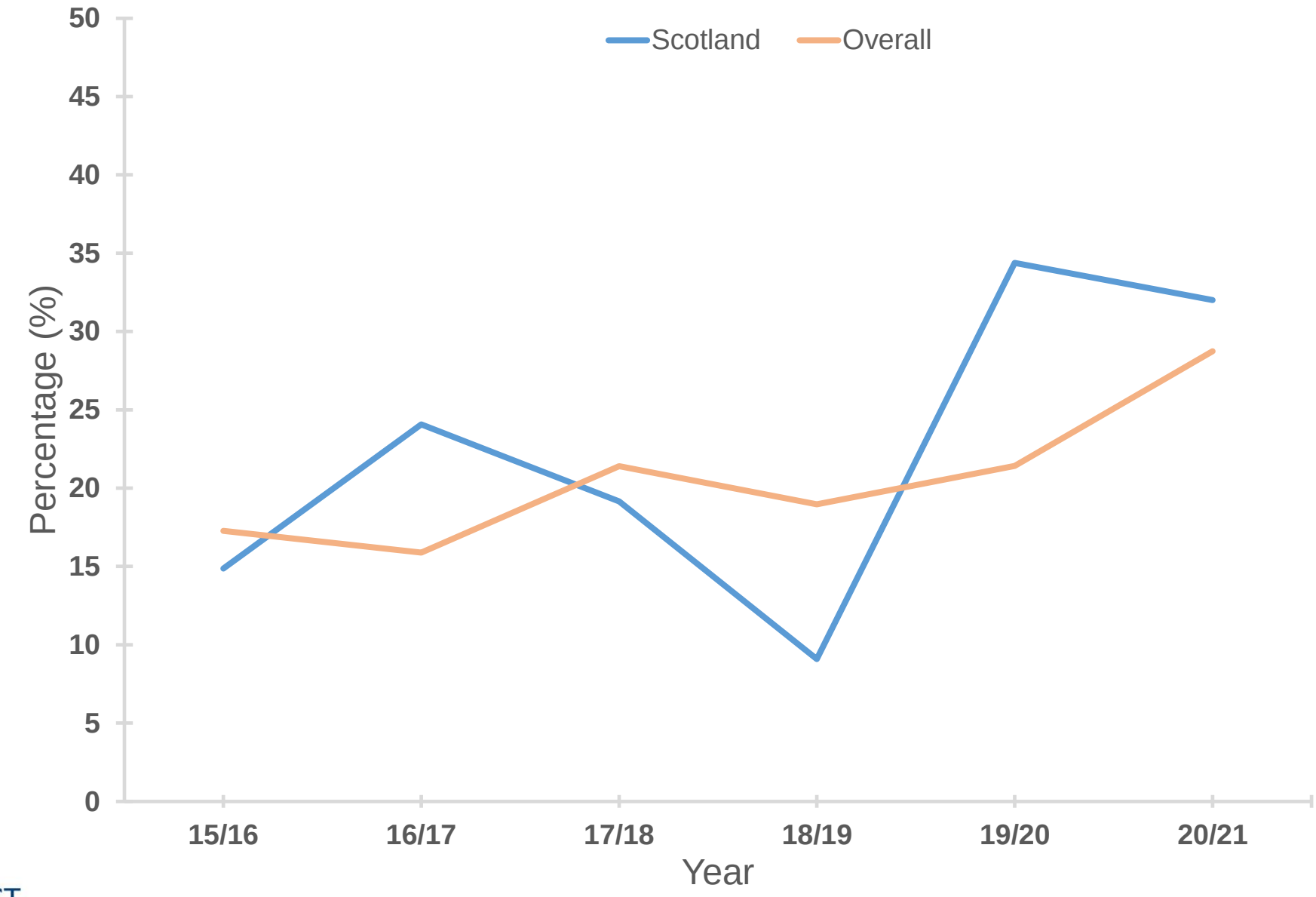
# Success Rates

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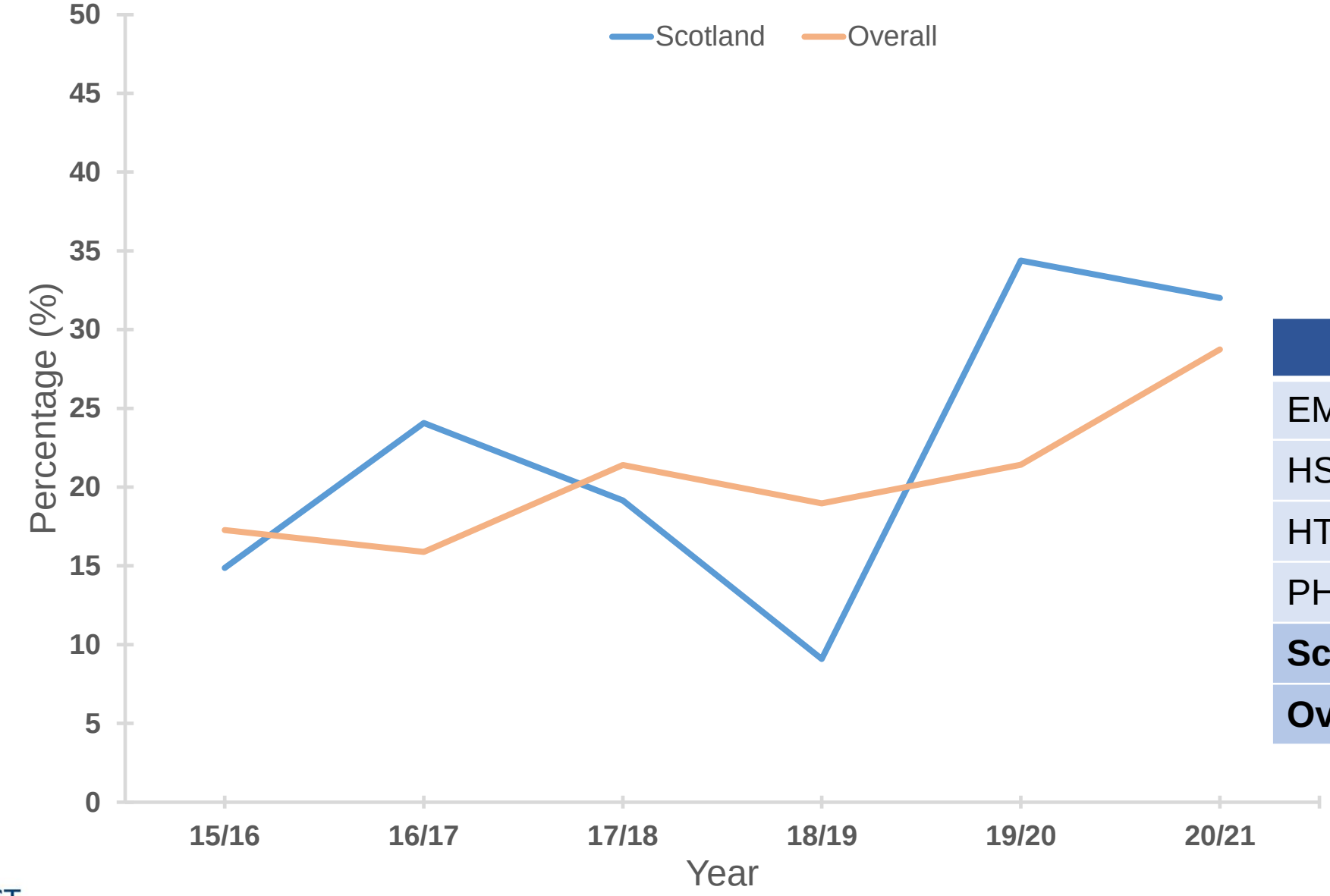
# Success Rates




| | Average |
|---|---|
| EME | 18 % |
| HSDR | 13 % |
| HTA | 25 % |
| PHR | 23 % |
| **Scotland** | **22 %** |
| **Overall** | **21 %** |

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# SCOTTISH NETSCC FUNDING

| EME | 17/18 | 18/19 | 19/20 | 20/21 |
|---|---|---|---|---|
| Scottish Funding | £0 | £0 | £0 | £2,013,271 |
| Total Funding | £16,238,013 | £21,589,419 | £24,449,333 | £28,368,659 |
| **Share of Funding** | **0 %** | **0 %** | **0 %** | **7 %** |
| **HSDR*** | | | | |
| Scottish Funding | £0 | £0 | £3,013,846 | £822,009 |
| Total Funding | £12,587,035 | £13,674,823 | £14,612,616 | £21,211,349 |
| **Share of Funding** | **0 %** | **0 %** | **21 %** | **4%** |
| **HTA** | | | | |
| Scottish Funding | £9,536,298 | £4,733,713 | £13,588,252 | £13,107,760 |
| Total Funding | £118,703,076 | £112,119,368 | £96,225,512 | £135,753,840 |
| **Share of Funding** | **8 %** | **4 %** | **14 %** | **10 %** |
| **PHR** | | | | |
| Scottish Funding | £375,946 | £973,153 | £6,479,781 | £2,299,924 |
| Total Funding | £15,998,716 | £13,084,904 | £25,952,170 | £29,436,877 |
| **Share of Funding** | **2 %** | **7 %** | **25 %** | **8 %** |

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*Research led only

# DR LISA DOUET

## SENIOR RESEARCH MANAGER

## NETSCC

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NIHR | National Institute for Health and Care Research

# National Institute for Health and Care Research

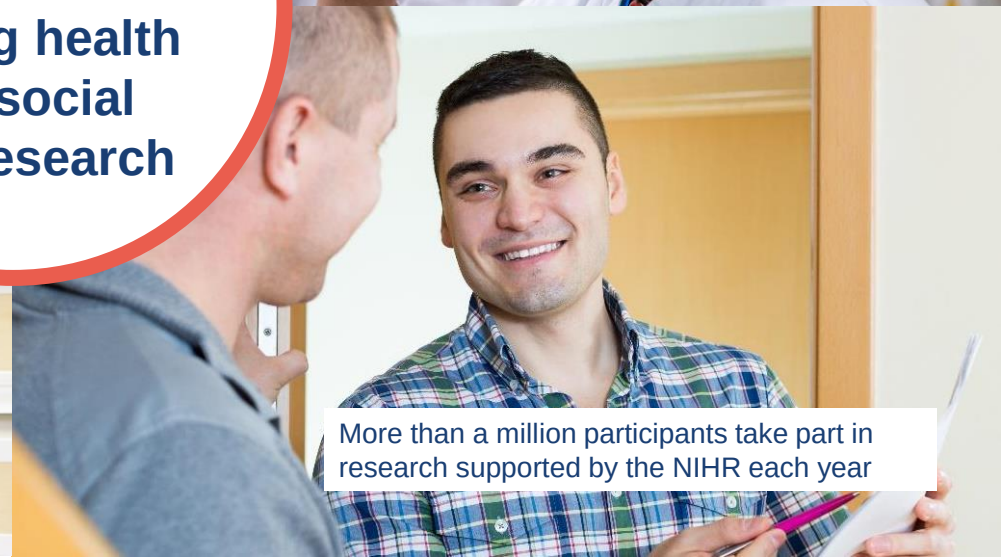
Dr Lisa Douet
NETSCC and the RDS

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

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

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

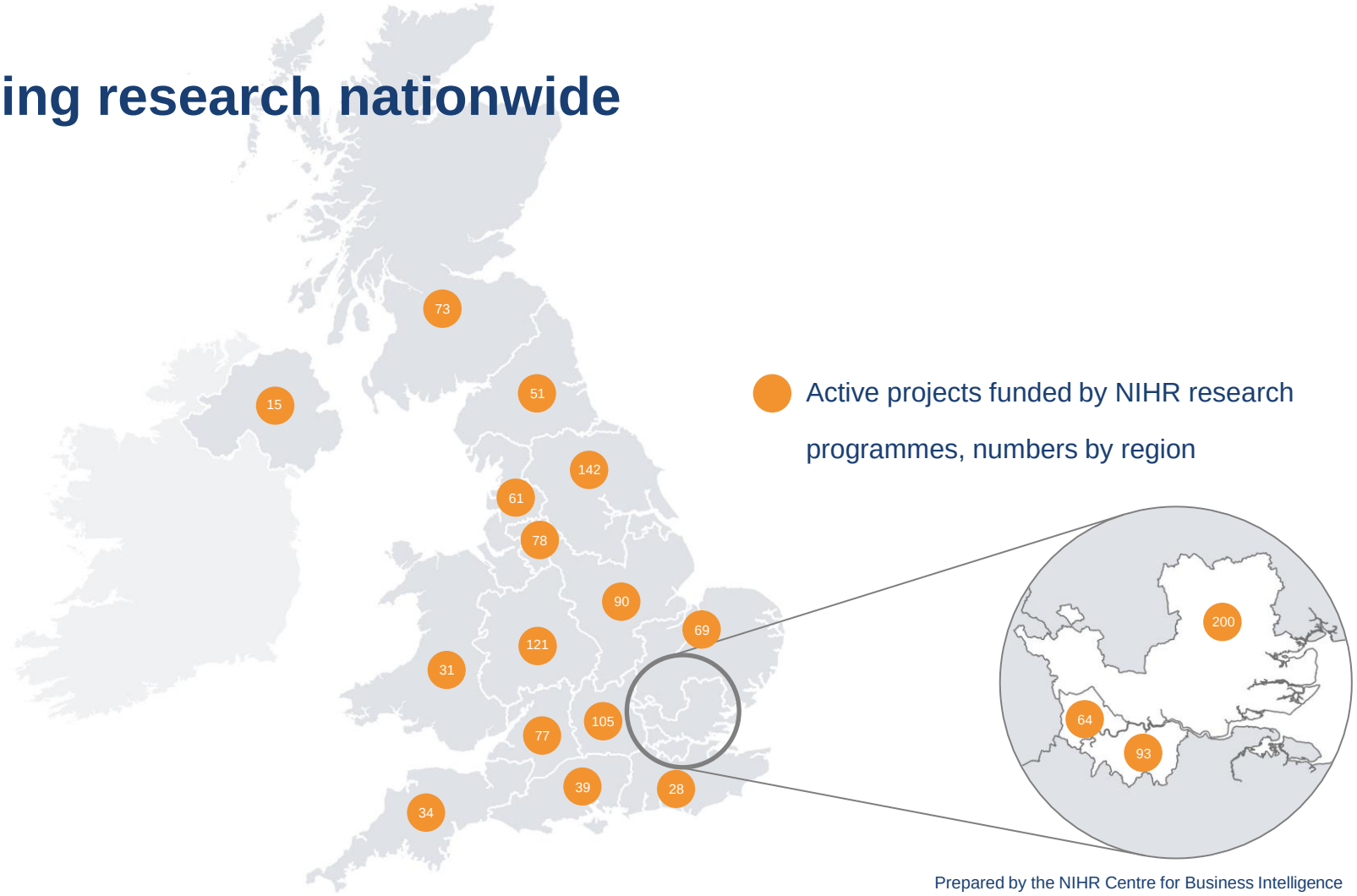
**Funding applied global health research and training** to meet the needs of the poorest people in low and middle income countries

www.nihr.ac.uk/about-us/what-we-do/

# Our areas of strategic focus


www.nihr.ac.uk/about-us/our-key-priorities/

# Funding research nationwide



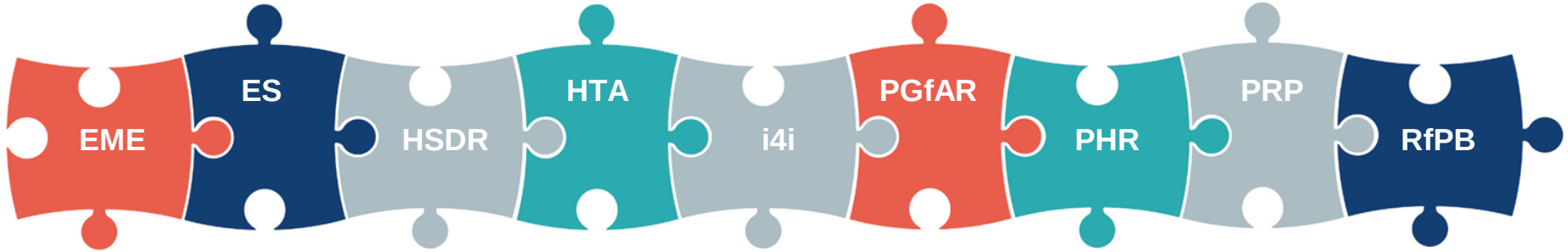

Active projects funded by NIHR research programmes, numbers by region

Prepared by the NIHR Centre for Business Intelligence

NIHR | National Institute for Health and Care Research

Latest data available here https://nihr.opendatasoft.com/pages/nihr-awards-filters/-value-of-awards#-value-of-awards

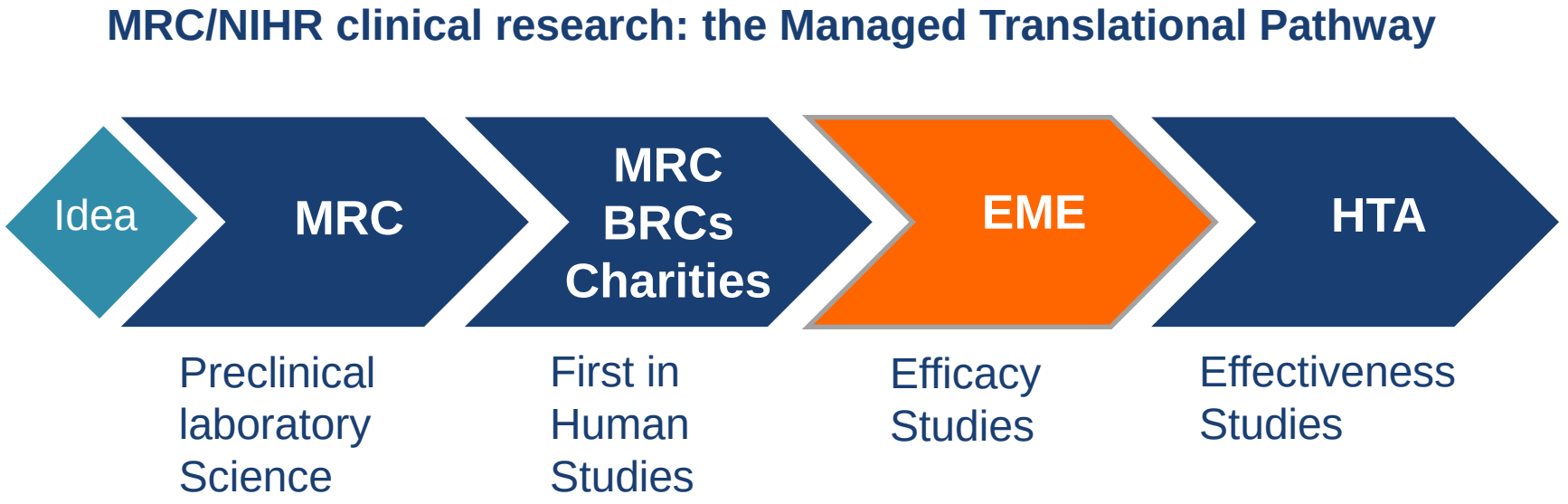
# Our research programmes




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

# The Managed translational pathway



# The EME Programme

- The Efficacy and Mechanism Evaluation (EME) Programme funds ambitious studies evaluating interventions with potential to make a step-change in the promotion of health, treatment of disease and improvement of rehabilitation or long-term care. Within these studies, EME supports research in the mechanisms of diseases and treatments.
- 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.

# The EME Programme

- What EME will **NOT** 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.

# The EME Programme

- To continue to fund ambitious projects which include new ways of delivering clinical studies that could:

- Maximise the potential gain from the research.
- Reduce the time or cost to evaluate promising new interventions.
- Increase the breadth of the programmes portfolio in terms of the types of interventions being evaluated and the methodologies being used.
- Increase the number and extent of collaborations, acknowledging that there is a potential for very large and ambitious studies.

- The EME Programme is a partnership between the MRC and NIHR.

# The HTA Programme

- The Health Technology Assessment (HTA) Programme funds research about the clinical and cost-effectiveness, and broader impact of healthcare treatments and tests, for those who plan, provide or receive care from NHS, and social care services.
- The Health Technology Assessment (HTA) Programme supports research that is immediately useful to patients, clinical practice, and policy or decision makers.

- HTA research is undertaken when evidence exists to show that a technology can be effective. The purpose of an HTA study is to establish the clinical and cost-effectiveness for the NHS in comparison with the current best alternative(s).
- A study may also investigate uncertainty around a technology's place in the existing care pathway.

# The HTA Programme

- “Technologies” in this context mean any method used to promote health, prevent and treat disease, and improve rehabilitation or long-term care. They are not confined to new drugs and include any intervention used in the treatment, prevention or diagnosis of disease.

- Examples include:

- procedures
- drugs
- devices
- diagnostic tests
- settings of care
- screening programmes

# The HTA Programme

- The technology doesn't necessarily need to exist in current NHS practice, but a study would need to show that it could. Health Technology Assessment asks important questions about these technologies such as:

- when is counselling better than drug treatment for depression?
- what is the best operation for aortic aneurysms?
- should we screen for human papilloma virus when doing cervical smears?
- should aspirin be used for the primary prevention of cardiovascular disease?

# The HTA Programme

- The HTA Programme will support a range of methods including:
- systematic reviews
- economic models
- meta-analyses
- mixed-treatment comparisons
- expected Value of Information studies
- randomised controlled trials (unblinded, single-blinded, double-blinded, triple-blinded)
- non-randomised trials
- cohort studies (retrospective or prospective)
- adaptive designs
- modelling studies

# HSDR Programme

- The Health and Social Care Delivery Research (HSDR) Programme aims to produce rigorous and relevant evidence to improve the quality, accessibility and organisation of health and social care services.
- The HSDR programme funds evaluative research that has the potential to improve health and social care services.
- Research may be primary (qualitative and/or quantitative), secondary and evidence syntheses. Typical projects are mixed-methods studies with a clear focus on the organisation and quality of care.
- There should also be a focus on the experience of patients, staff and service users.
- Projects will often include an analysis of routine and linked data on service use, activity and outcomes.

# HSDR Programme

- A variety of study designs are considered and examples include:

- major implementation studies on stroke configuration
- pragmatic trials of risk stratification tools
- evaluation of complex frailty hubs
- evidence synthesis of strengths-based approaches to social work practice
- realist evaluation of intentional nursing rounds
- organisational studies on effective board governance
- ethnographic research on the experience of inpatients with dementia in hospital wards

# The PHR Programme

- The Public Health Research (PHR) Programme funds research to generate evidence to inform the delivery of non-NHS interventions, intended to improve the health of the public, and reduce inequalities in health.
- The primary aim of the programme is the evaluation of practical interventions which have the potential to be delivered at scale, in order to generate evidence to support public health decision making and lead to sustainable population level change. We will fund both primary research (mainly evaluative, but also some preparatory research) and secondary research (evidence synthesis); precise methods will need to be appropriate to the question being asked, and the feasibility of the research.

# The PHR Programme

- Our scope is multi-disciplinary and broad, covering a wide range of interventions that improve public health.

- The programme funds research to generate evidence to inform the delivery of non-NHS interventions, specifically, we provide new knowledge on the benefits, costs, acceptability and wider impacts of non-NHS interventions intended to improve the health of the public, and reduce inequalities in health.

- Proposed primary outcome measures should always be health-related, unless otherwise specified in a commissioning brief.

# The PHR Programme

- Example studies may include:
- studies evaluating interventions to reduce air pollution and model scenarios
- evaluations of transport and traffic initiatives
- evaluations of interventions to tackle obesity such as Football Fans in Training
- evaluation of an early years nutrition and physical activity intervention
- evaluations of community based initiatives such as Age-friendly environments
- the impacts of e-cigarette legislation on young people’s use of e-cigarettes

# The PHR Programme

- The PHR Programme is also keen to see applications for large-scale evaluation studies with the potential for national reach. This means primary research projects which:

- address an issue of major strategic public health importance, with the cost in line with the significance of the problem to be investigated
- are likely to lead to changes in practice that will have a significant impact on a large number of the population across the UK
- aim to fill a clear 'evidence gap', and likely to generate new knowledge
- have the potential for findings that are generalisable and transferable
- bring together a team with strong expertise and track record across the full range of relevant disciplines

# Programme workstreams

## 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 & public health settings.

Identify evidence gaps and stimulate ‘market failure’ research that may not otherwise be funded

## NIHR Themed Calls

Cross-NIHR calls on topics of national priority. 1-2 per year. Invite researchers to submit applications within a specific theme, e.g. obesity, dementia

# What makes a good topic?

- Important to the NHS, patients &/or the public
- Supported by current evidence
- High scientific quality
- Feasible
- Timely, *i.e.* research will continue to be relevant following completion of study
- Clear and well-defined
- Represents value for money
- 

# Preparing your proposal

- Read the guidance notes, commissioning brief and supporting information referenced.
- Structure your research plan in the format it suggests.
- Keep to the remit of the Programme you are applying and address individual requirements of that Programme.
    - For example EME, proof of concept
- If your study spans more than one Programme, a strong justification should be included as to why this study is required.

# Research Question

- Is it the most important question, clearly defined in simple terms, ideally in one sentence?
  - Has the question already been answered?
  - Has a similar project already been funded by the funders?
  - Does it matter to patients/public?
  - Is it timely and will it make a difference?
  - Can it be delivered by the NHS/Social Care?

# Study design

- Is the design optimised to answer the question?
  - Use existing support, e.g. RDS, CTU
  - Choose the most robust research method and describe it clearly and fully.
  - Ensure your choice of primary outcome, and any secondary outcomes are clear.
  - Statistical input: can your sample size/power calculation be replicated?
  - Explain the dose and any side effects of the intervention.

# Multi-disciplinary team

- Do you have the expertise you need?
  - Ensure the roles are clearly defined and appropriate
  - Consider the level and range of expertise required
  - Ensure that PPI is demonstrated at all stages – involve PPI early

# Deliverability

- Have you ensured your research is credible?
  - Recruitment: have you made a convincing case that your recruitment plan is realistic?
  - Is your timeline manageable?
  - Does your application provide value for money, and are the costs correctly allocated?
  - What is the current evidence?
  - Will the study show what you want it to?

# Research Dissemination and Impact:

- 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?

# Feedback

- Have you followed the feedback, or made a robust defence for why you disagree?
  - External Reviewers
  - Funding Committee Members

NIHR | National Institute for Health and Care Research

# Any questions?

# PROF ANDREW HORNE
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# Using CSO funding to secure an NIHR grant:

## *a personal experience*

Professor Andrew Horne

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**EME 13/52/04 -** GaPP2: A multi-centre randomised controlled trial of the efficacy and mechanism of action of gabapentin for the management of chronic pelvic pain in women (*complete*)

**HTA NIHR129801 -** ESPriT2: A multi-centre randomised controlled trial to determine the effectiveness of laparoscopic treatment of isolated superficial peritoneal endometriosis for the management of chronic pelvic pain in women (*recruiting*)

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# Background to the GaPP2 trial question

- Chronic pelvic pain affects 2–24% of women worldwide
- Associated with reduced quality of life and 45% reduction in work productivity
- Pelvic pain where no cause is identified at laparoscopy is often difficult to manage
- Off-label use of gabapentin for chronic pelvic pain has increased because of proven efficacy in other chronic pain conditions
  - 74% of GPs surveyed said that they would consider gabapentin as a treatment option
  - 50% of gynaecologists surveyed said that they currently prescribe gabapentin for chronic pelvic pain
  - Despite side effects and potential addictive qualities
- Data from randomised clinical trials of the use of gabapentin in women with chronic pelvic pain are scarce



*Daniels et al. BMJ 2010*


- One trial compared efficacy of gabapentin and amitriptyline for chronic pelvic pain in women with a range of pelvic pathologies (n=56)
- Randomised to receive either gabapentin or amitriptyline
  - No placebo arm
- At 24 months gabapentin improved pain scores on a VAS (0-10)
  - Mean pain score in gabapentin group 1.5 points lower than in amitriptyline group (95% CI −2.06 to −0.94)



*Sator-Katzenschlager et al. Wien Klin Wochenschr 2005*

# Application for a full trial (2010) to NIHR EME

***multicentre randomised controlled trial to determine the efficacy of gabapentin in chronic pelvic pain in women***

"No pilot data to support feasibility"

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# Application to CSO to fund a pilot trial (2011)

- Response mode funding scheme
  - Limit £300,000 (FEC)
  - Translational Clinical Studies Research Committee
- Outline proposal
  - 4 pages
- Full application
  - 6 weeks to submit after outcome of outline proposal
  - sent to independent peer-reviewers and also three committee members
  - applicants asked to respond to reviewers' comments and given one week to do so

# GaPP1

***two-arm randomised controlled pilot trial***

- 60 women with chronic pelvic pain in two centres
- Randomised to gabapentin or placebo
- Response to treatment monitored by questionnaires at 0, 3 and 6 months
- Primary objective to assess recruitment and retention rates
- Secondary objectives
  - To determine the effectiveness and acceptability to participants of the proposed methods of recruitment, randomisation, drug treatments and assessment tools
  - To perform a pretrial cost-effectiveness assessment of treatment with gabapentin

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*Horne et al. BMJ Open 2012; Lewis et al. PLoS One 2016*

# GaPP1

***two-arm randomised controlled pilot trial***

- Participants on gabapentin
  - Lower pain severity
  - BPI difference 1.72 points on a 11 point scale, 95% CI 0.07 to 3.36
- Greater improvement in mood
  - HADS difference 4.35 points, 95% CI 1.97 to 6.73
- 17/22 gabapentin participants had an adverse event compared with 16/25 in the placebo group
  - Most events were mild, such as drowsiness
- The majority of the participants described their trial experience favourably
  - Acceptability questionnaire
  - Focus groups

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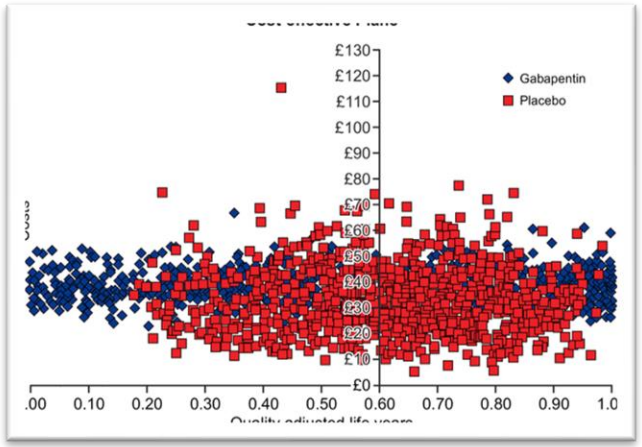
*Horne et al. BMJ Open 2012; Lewis et al. PLoS One 2016*

# GaPP1

***Is gabapentin cost-effective?***

- Probabilistic decision analytical model
- At a willingness-to-pay of £20,000 to £30,000, gabapentin has a greater probability of being cost-effective than placebo at a probability of 60%





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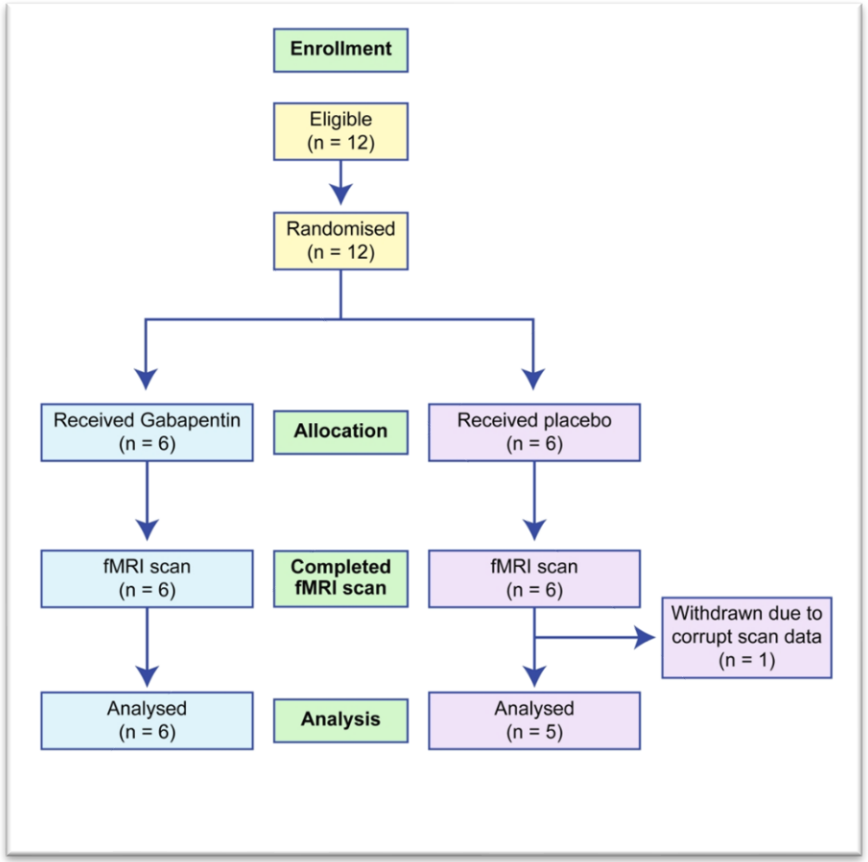
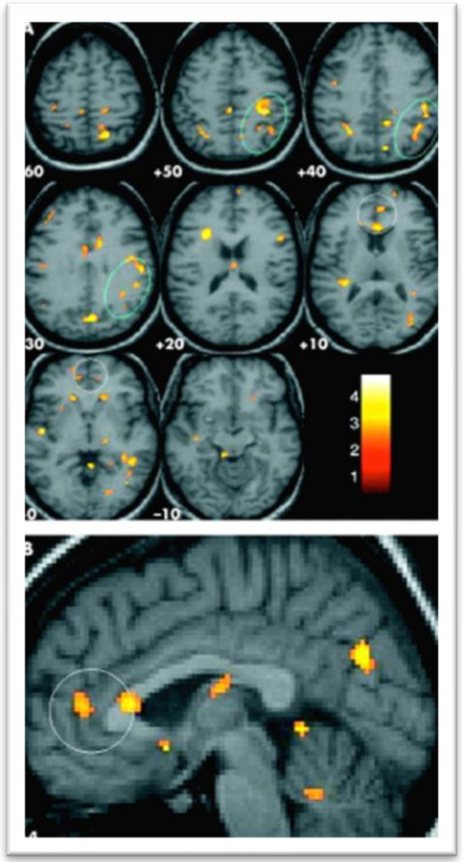
*Horne et al. BMJ Open 2012; Lewis et al. PLoS One 2016*

# GaPP1

***embedded mechanistic functional MRI brain study***



Seretny et al. BMJ Open 2019

# 2013 NIHR Commissioned call

## *Trials in 'chronic pain'*

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# GaPP 2

CLINICAL TRIAL TO DETERMINE THE EFFICACY OF GABAPENTIN FOR THE MANAGEMENT OF CHRONIC PELVIC PAIN IN WOMEN

- Demonstrated feasibility in the pilot
- Used the pilot to inform trial design
  - sample size calculation
  - number of sites
  - dosing regimen
  - primary outcome
  - outcome measure tools
    - text messaging system
    - questionnaires

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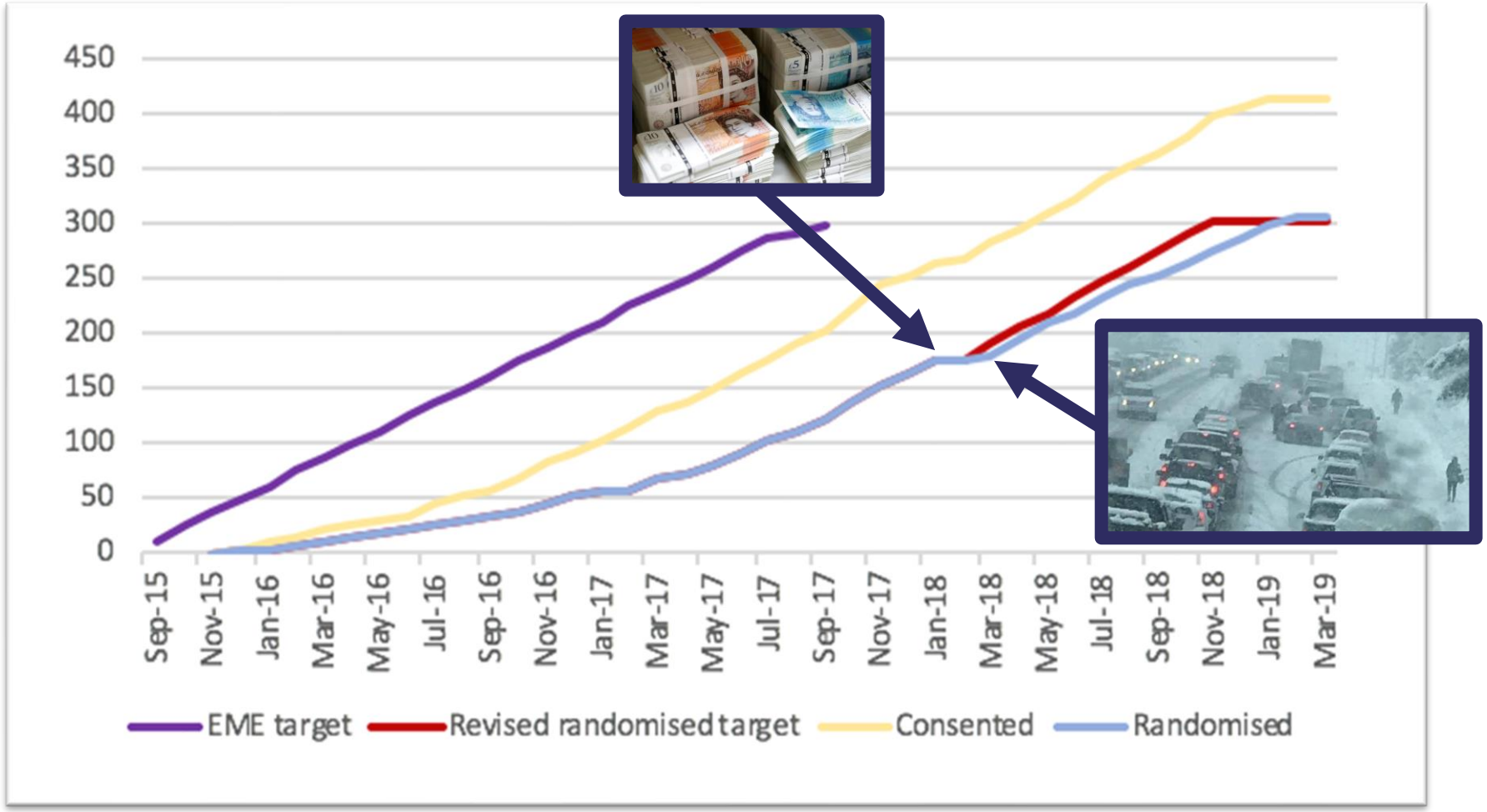
*Vincent et al. BMJ Open 2018*

# GaPP 2

CLINICAL TRIAL TO DETERMINE THE EFFICACY OF GABAPENTIN FOR THE MANAGEMENT OF CHRONIC PELVIC PAIN IN WOMEN

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*Horne at al. BMJ 2017; Vincent et al. BMJ Open 2018*

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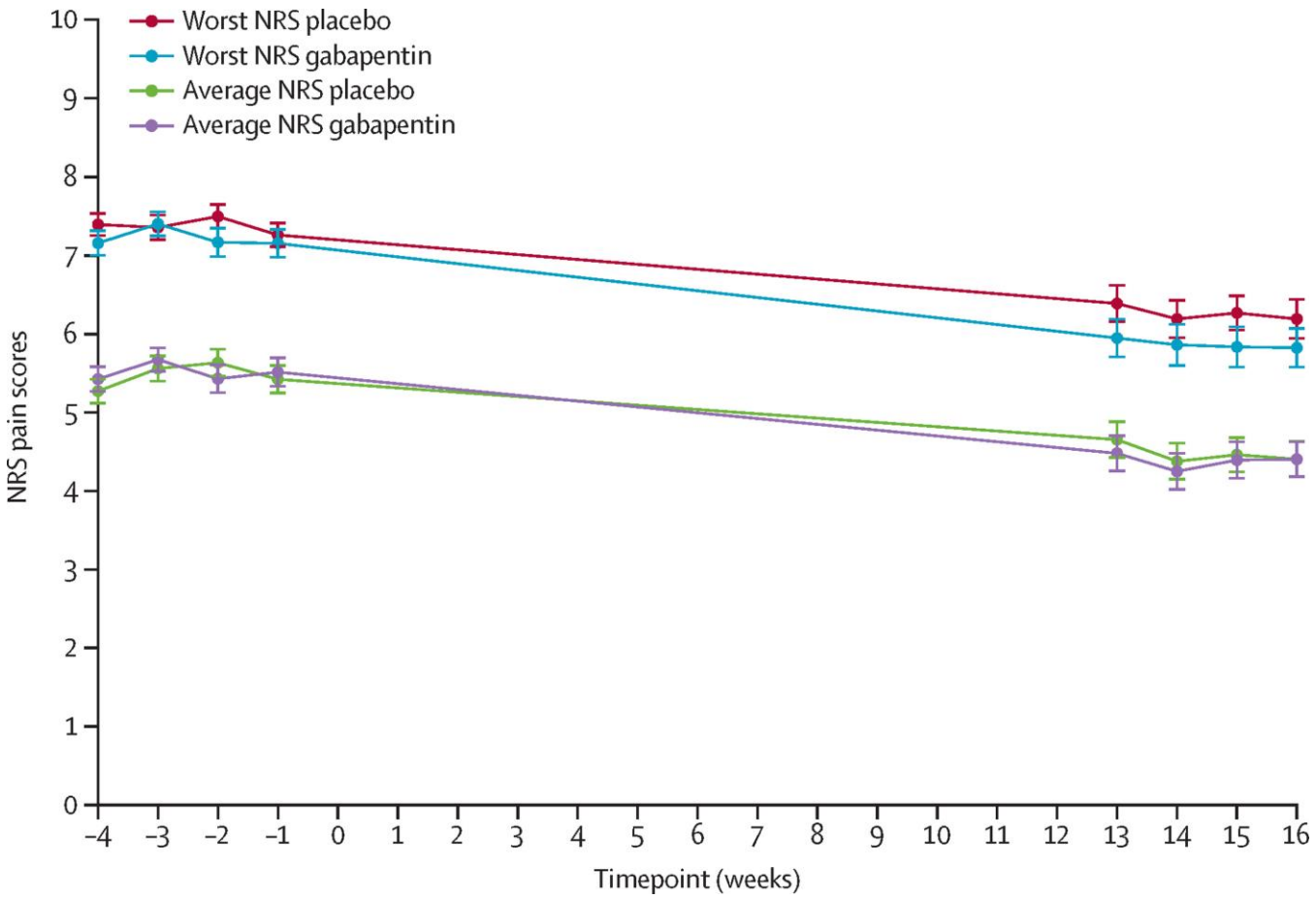


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*Horne at al. Lancet 2020*

# GaPP 2

CLINICAL TRIAL TO DETERMINE THE EFFICACY OF GABAPENTIN FOR THE MANAGEMENT OF CHRONIC PELVIC PAIN IN WOMEN

| | Gabapentin (n=153) | Placebo (n=153) | Risk ratio* (99% CI) | p value |
|---|---|---|---|---|
| **Side-effects** | | | | |
| Dizzy | 66/122 (54%) | 32/114 (28%) | 1·91 (1·22–2·99) | 0·0002 |
| Tired | 85/129 (66%) | 68/120 (57%) | 1·12 (0·86–1·44) | 0·3 |
| Drowsy | 64/124 (52%) | 34/116 (29%) | 1·71 (1·09–2·68) | 0·002 |
| Change in mood | 55/118 (47%) | 43/112 (38%) | 1·17 (0·79–1·74) | 0·3 |
| Change in urinary pattern | 37/114 (32%) | 35/111 (32%) | 1·00 (0·61–1·63) | 1·0 |
| Visual disturbances | 25/113 (22%) | 12/110 (11%) | 2·25 (0·99–5·10) | 0·01 |
| Change in skin | 31/112 (28%) | 23/110 (21%) | 1·35 (0·74–2·50) | 0·2 |
| Different pain | 33/116 (28%) | 37/117 (32%) | 0·88 (0·53–1·46) | 0·5 |
| Shortness of breath | 17/114 (15%) | 11/109 (10%) | 1·45 (0·57–3·71) | 0·3 |
| **Adverse events** | | | | |
| Serious adverse event | 10/153 (7%) | 3/153 (2%) | .. | 0·04 |

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*Horne at al. Lancet 2020*

# GaPP 2 | CLINICAL TRIAL TO DETERMINE THE EFFICACY OF GABAPENTIN FOR THE MANAGEMENT OF CHRONIC PELVIC PAIN IN WOMEN

- ***First large, randomised, placebo-controlled clinical trial to report on treatment of chronic pelvic pain with gabapentin***
- Robust study design, including masking to treatment allocation of both participants and investigators, ensures internal validity, enabling the results to be interpreted with confidence
- Groups were balanced with respect to dysmenorrhea, psychological distress, and concomitant use of hormonal contraceptives—all potentially prognostic for reported pain
- Design of our trial reflects the real-word choices that women and their gynaecologists make about the management of chronic pelvic pain
- ***We can confidently conclude that gabapentin is not effective for chronic pelvic pain in women***



*Horne at al. Lancet 2020*

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# CSO funding can lead to substantive NIHR funding

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# Health Technology Assessment (HTA)
# What makes a good application?

Rebecca Reynolds

Professor of Metabolic Medicine

University of Edinburgh

# Disclaimer

- I am a panel member of the
  - HTA Commissioned Funding Committee (since 2019)
  - HTA Funding Committee Policy Group (since 2021)
- I have current NIHR funding
  - HTA funded RCT – STOPPIT-3 (Co-I)
  - EME-funded mechanistic study embedded within the trial - STOPPIT-M (PI)
  - NIHR Global Health Group in Malawi (Co-I)
- I have had several grant applications rejected by both HTA and EME including 2 this year!
- My presentation reflects my own views

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# HTA Scope

- funds research about the clinical and cost-effectiveness, and broader impact of ‘technology’ i.e. healthcare treatments and tests
- supports research that is immediately useful to patients, clinical practice, and policy or decision makers
- HTA research is undertaken when evidence exists to show that a technology can be effective

# Overview of process

**3 funding streams**

- Commissioned calls
- Researcher Led
- James Lind Alliance Priority Setting Partnership calls

- Panels meet 3 times a year

- Applications are submitted via NIHR REALMS portal

# Overview of process

**Stage 1 application**

- All panel members read all applications
- Lead DCM + 2 panel members (one usually a statistician) present strengths and limitations of the application to the rest of the panel and recommend whether they would like to see a full application. Panel vote as to whether goes through
- Panel will give recommendations for changes to be included in the stage 2 application

# Overview of process

**Stage 2 application**

- Application will be sent for expert peer review
- Similar process with DCM presenting strengths and limitations to the panel
- All panellists score the application
- Recommend for funding with changes

Some calls are straight to Stage 2

# 5 Top Tips
# and Common Pitfalls

# Tip 1: Be prepared

- Keep an eye on the NIHR website as commissioned calls are advertised in advance
- For commissioned calls – stick to the brief
- For researcher led – need to convince panel of the importance of the research question
- Speak to your trials unit early on
- Ask a critical friend to peer-review – your stage 1 application will likely be read by a non-expert
- Allow time to refine
- Check character count for each section to avoid last minute need to precis

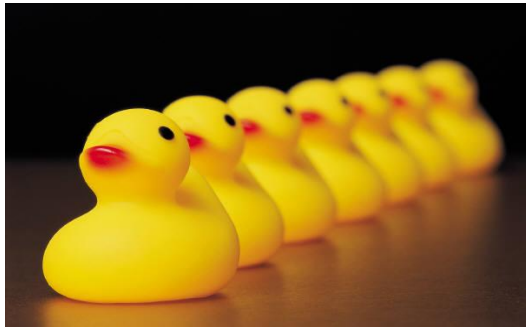
# Tip 2: PPI

- Essential to do well
- Need to demonstrate how PPI has informed the research and how PPI will be embedded throughout the research
- Invite PPI to read your lay summary
- Consideration of inclusion of underserved populations and vulnerable groups
- Resources on NIHR website e.g. INVOLVE, INCLUDE ethnicity framework principles

# Tip 3: Methodology


- Clearly describe **both** the Intervention and Treatment as Usual Pathways
- Carefully consider your study design – keep as simple as possible
- Engage your statistician early
  - Your sample size calculation will be reproduced
  - Be realistic about drop-outs
  - Justify your effect size
  - HTA require studies to have 90% power
- If including a pilot, have robust stop/go criteria

# Tip 4: Co-applicants



- Need to demonstrate have expertise to deliver the work
- Junior/Senior Co-lead
- Justify numbers of co-applicants – particularly if lots from the same specialty
- Consider Co-I time as this can quickly make a grant become expensive
- Ensure you have PPI members

# Tip 5: Costs


- HTA want to see value for money
- Make sure you have included appropriate costs for PPI
- Try and keep your Stage 2 costs as close to what you submitted at Stage 1 as these will be compared

Thankyou
and Good Luck!

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# NIHR Public Health Research programme

**S Vittal Katikireddi**

*Professor of Public Health & Health Inequalities*

MRC/CSO Social and Public Health Sciences Unit, University of Glasgow

24th October 2022

E-mail: vittal.katikireddi@glasgow.ac.uk

Twitter: @vkatikireddi

# My experience

- Member of NIHR PHR Funding Committee since 2016
  - Observed NIHR PHR Prioritisation Committee
- Member of other NIHR cross-programme panels e.g. Long COVID, Long COVID in children, Liver Disease
- Recipient of NIHR PHR funding for primary research, evidence synthesis and policy simulation modelling
- N.B. Providing my own personal views, not NIHR policy or the views of the Funding Committee

# PHR remit

- The Public Health Research (PHR) Programme funds research to generate evidence to inform the delivery of **non-NHS** interventions, intended to improve the health of the public, and reduce inequalities in health.
- Examples:
  - Transport and traffic initiatives
  - Food policy e.g. sugary drinks levy, takeaway food outlet policy
  - Welfare policy e.g. Universal Credit
  - Alcohol and tobacco policy e.g. Minimum Unit Pricing, Smoke-free prisons
  - School interventions
- In theory, no funding limit but rare to be >£2M
- Intervention costs not usually funded

# Standard application process

- Stage 1 Outline
  - Short form (but good to start with stage 2 paperwork)
  - Assessed by Prioritisation Committee: comprises public health practitioners and policymakers e.g. DPHs within LAs, OHID etc.
  - If above threshold, goes to Funding Committee: diverse academics (PH, psychologists, trialists, stats, qual researchers, SRs, health economists) and PPI members
- Feedback from FC
- Stage 2 Full
  - Long form and detailed research proposal
  - Subject to peer review
  - Three DCMs provide detailed written assessments in advance and all panel members discuss

# Tips for successful applications

- Important PH topic
  - Intervention development should not be part of application – go to MRC PHIND – but refinement is OK.
- Relevant expertise
  - Often includes topic expertise, stats, qual, health economics and trials/SRs (if relevant)
- Robust study design
  - Methods should be as strong as possible
  - RCTs if feasible – consider pilot/feasibility with clear progression criteria
  - NE studies if RCTs not feasible
- Embed PPI

# Tips 2

- Comprehensive approach usually preferred
  - Intervention effectiveness
  - Process evaluation
  - Unintended/secondary impacts
  - Health economics
  - (For SRs: might include meta-analyses, meta-regression, intervention component analysis, health economics etc.)
- Logic model / Systems map
  - Use theory to demonstrate how intervention impacts on outcomes
  - Role of context
- Focus on health inequalities – consider multiple axes of inequality and potential for intersectional approaches etc.

# Tips 3

- Pay attention to panel feedback
  - Remember that the panel will assess your response
- Letters of support
  - Can be helpful to demonstrate importance, policy interest and feasibility
- Costs should not change between stage 1 and stage 2 (except to address issues raised by the panel)
- Value for money
  - PHR is less well resourced than some other NIHR panels, so will scrutinise costs closely

# Tips 4

- Ensure you draw on relevant guidance e.g.
  - MRC guidance on complex interventions / natural experiment studies
  - TIDIER/TIDIER-PHP (for describing interventions)
  - INVOLVE (for PPI)
- Read all the available guidance carefully
  - The secretariat are usually very helpful – get in touch if unsure

- (For England: Research Design Service but co-applicants in England might be able to access this)

# Common pitfalls

- Confusing or poorly written applications – difficult to follow what's going on and why
- Poor study design e.g. no or poorly defined control group
- No/poor logic model
- Inadequate preparation – demonstration of feasibility is important
- No health outcome
- Lack of expertise
- Lack of track record – but more junior staff can be supported to be Co-PI if backed up by mentorship plans
- Lack of PPI – should show evidence of how it has informed development and need a good lay summary

# Other funding schemes

- Fast-track scheme – if need to study some time-sensitive intervention
- Public Health Intervention Responsive Studies Teams (PHIRST) scheme – links academics to evaluate local PH initiatives, largely within local authorities
- Health Determinants Research Collaborations – partnerships to boost local authorities ability to conduct research to tackle health inequalities

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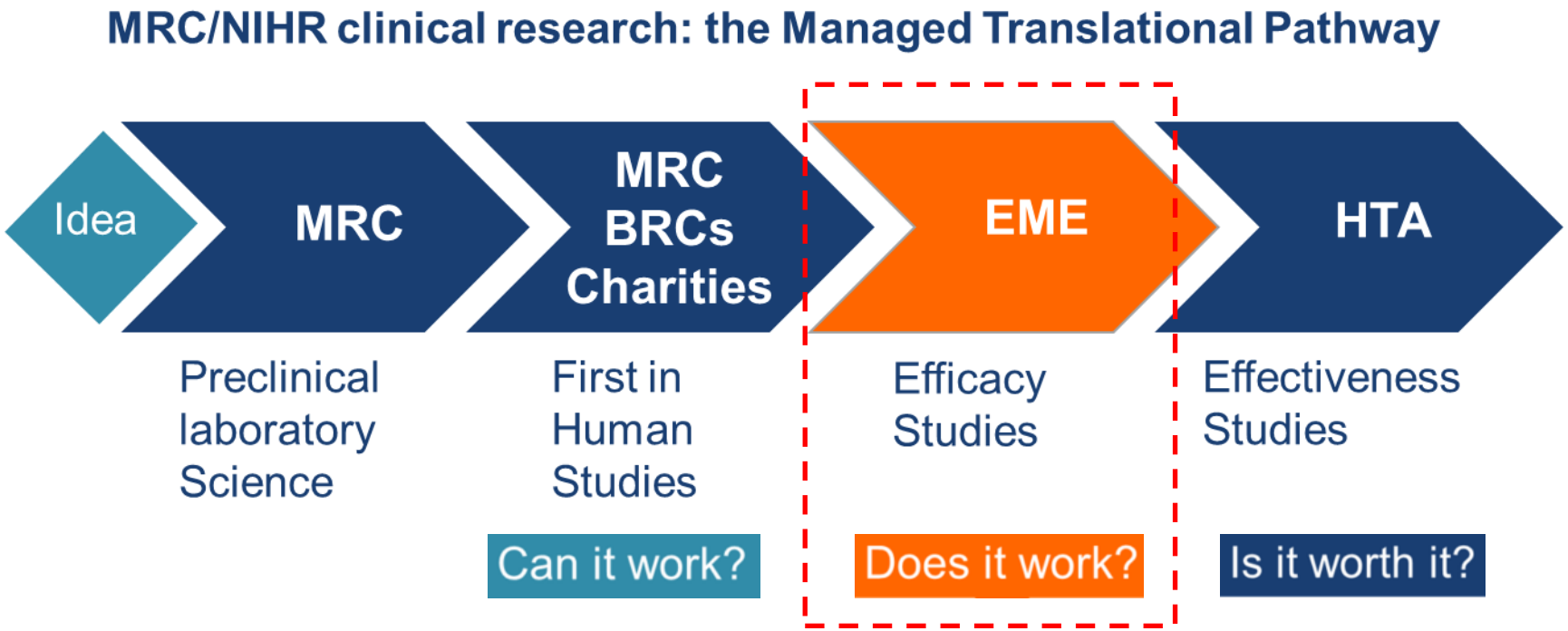
# Efficacy and Mechanism Evaluation Programme (EME)

John Petrie

Deputy Chair

October 2022

# UK biomedical research funding



# EME funds hypothesis-driven research:

- to determine **proof of clinical efficacy**, size of effect, and safety in a well-defined population
- to evaluate (a broad range of) interventions which have the potential to **maintain health, treat disease or improve recovery**
- to explore the **mechanisms of action** of interventions, causes of differing responses or disease mechanisms
- using study designs which increase value by maximising the chances of demonstrating the benefit of an intervention, or increasing the knowledge that can be gained

*Also:*

- *embedded pilot and feasibility studies for which the main study would be within the remit of the EME programme*
- *final development of an intervention prior to proceeding to the main clinical evaluation within the same application*

# EME particularly wants to see research involving:

- patient stratification
- methodological innovation
- broader diversity of interventions
- novel use of information enabled by digital technology

# EME does not fund:

- effectiveness studies (testing 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
- animal research

# Researcher-led “rolling” call:

- **Efficacy studies** to evaluate the efficacy of a wide range of interventions, where there is some human ‘proof-of-concept’, i.e. a signal that the technology may work.
- **Mechanistic studies** to test hypotheses around the mechanism of action of an intervention, making use of patients, data or samples from other studies.
- **Combined Efficacy and Mechanistic studies** which both evaluate an intervention and test hypotheses around its mechanism of action within the same study

# Check also for commissioned calls:

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

**Latest funding opportunities for Efficacy and Mechanism Evaluation**

22/111 Mechanism of action of social care interventions

The Efficacy and Mechanism Evaluation (EME) Programme is accepting stage 1 applications to their commissioned workstream.

22/106 Delivering a sustainable health and care system (EME Programme)

The Efficacy and Mechanism Evaluation (EME) Programme are accepting stage 1 applications to this NIHR Themed Call for research into the evaluation of interventions or services to support the delivery of a more sustainable UK health and care system, including mitigating the effects of climate change on health and care delivery.

22/107 Motor neurone disease highlight notice (EME Programme)

The Efficacy and Mechanism Evaluation (EME) Programme is accepting stage one applications to this funding opportunity.

22/108 Pain management for children and young people (0-19 years)

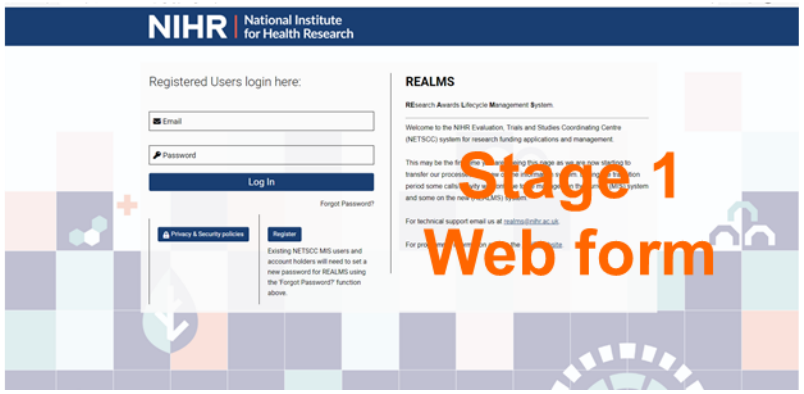
The Efficacy and Mechanism Evaluation (EME) Programme is accepting stage 1 applications to their commissioned workstream.

22/105 NIHR James Lind Alliance Priority Setting Partnerships rolling call (EME Programme)

The Efficacy and Mechanism Evaluation (EME) Programme is accepting stage 1 applications to this funding opportunity. The programme recognises the importance of the research priorities identified by the James Lind Alliance (JLA) Priority Setting Partnerships (PSP) and are interested in receiving high-quality applications which address them.

# The Application and Funding Process

**Stage 1 Application Process**




Stage 1 application

Pre-filter (Remit & competitiveness panel)

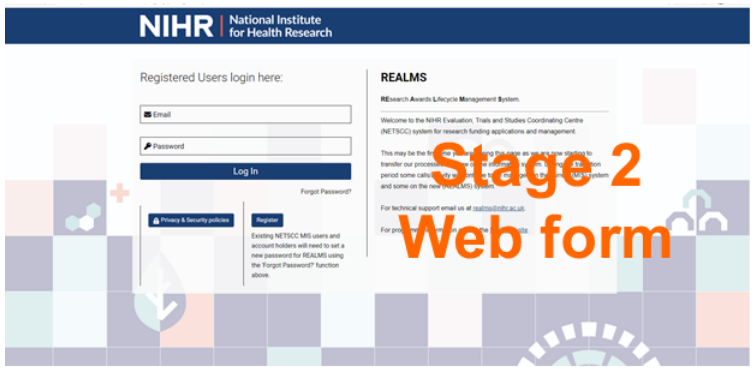
Designated Committee Members (DCMs) selected

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

# Key points for review (1)

- Case for research – importance, other relevant (ongoing) research, genuine gap?

- "PICO":
  - Patients/Population – who/what
  - Intervention – how
  - Comparator – placebo/ standard of care
  - Outcome – justify (primary, secondary)

- Proportionate proof of concept:
  - depending on the size of the translational step, the scale of the study, the cost requested and the nature of the intervention

# Key points for review (2)

- ensure multi-disciplinary expertise in **team**
- methods to protect against **bias/ confounding**
- ensure the **sample size calculation** be replicated
- **added value of any mechanistic component**
- **feasibility** of recruitment plan
- **ethical** issues

N.B. Research Design Service, Clinical Trials Unit

# Key points for review (3)

- recruitment plan - realistic?
- equality, diversity and inclusion?
- timeline manageable?
- value for money?
- costs correctly allocated? c.f. AcoRD guidance

# Patient and Public Involvement and Engagement (PPIE)

- Pre-application - and going forward
- PPI co-applicant, PPI lead, PPI representatives (named – numbers)
- Adequate costings (reimbursement)
- Independent voices, diversity, education opportunities, deprofessionalise
- Plain English Summary:
  - avoid words > 2-3 syllables
  - 11 year old reading age (e.g. use Gunning-Fog Index)
- N.B. Involvement of “special interest groups” can be valuable but does not replace PPIE
- Importance cannot be overstated!

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## Contact us

eme@nihr.ac.uk

## Useful resources

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

# PROF STEPHEN TURNER

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# NIHR funding – a researcher's experience

Steve Turner

24th Oct 2022

Consultant Paediatrician NHG Grampian

# Overview

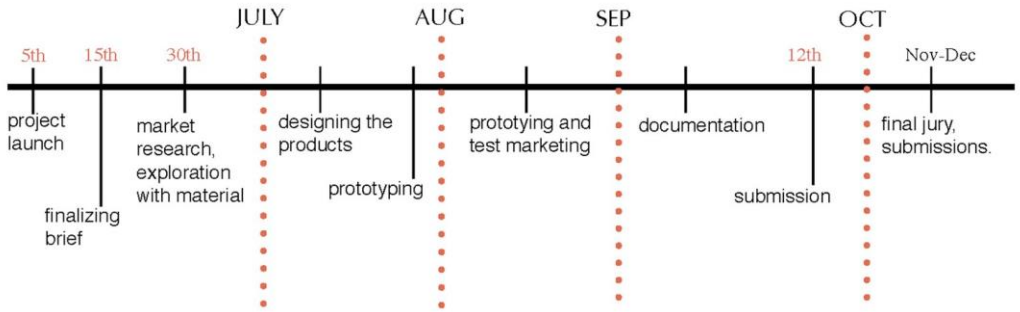
- Explain the clinical setting
- Describe the time lines of EME bid #1
- Then EME bid #2
- And finally EME bid #3
- Not getting into
  - EME versus HTA (efficacy versus efficiency)
  - Level of evidence
  - etc

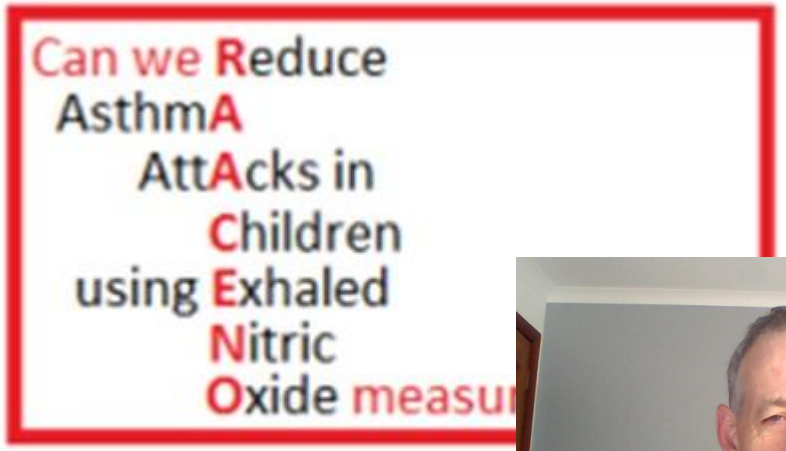

# What started it all off?

- Initially there was no plan
- Asthma researcher
- 2014
  - Write review
  - Promotion failed (“Steve you need a big grant”)
- Exhaled nitric oxide
  - Is it useful or not?
  - Eight clinical trials
  - Glimmer of evidence
  - Some enthusiasts, many doubters


# Time lines

- Jun-Dec 15.  Work up initial submission
  - The team
  - Feasibility (previous CSO funded study)
  - PPI work (asthma UK)
- Apr 16.  Offer to submit full application
  - In May
  - Most of work done (for me)

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  - PPI work (asthma UK)
- Apr 16.  Offer to submit full application
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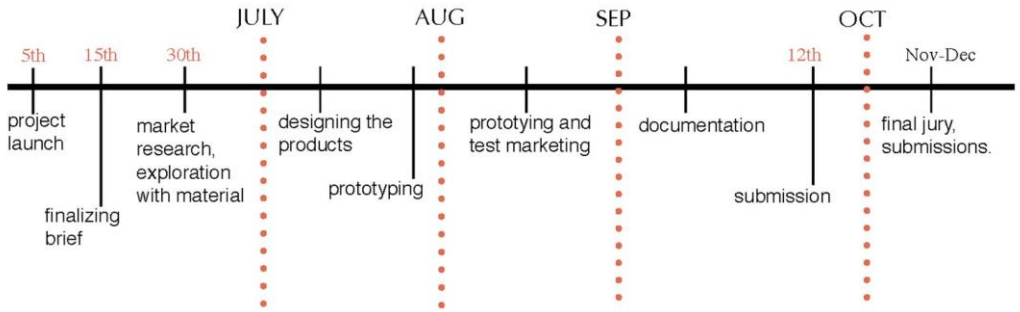
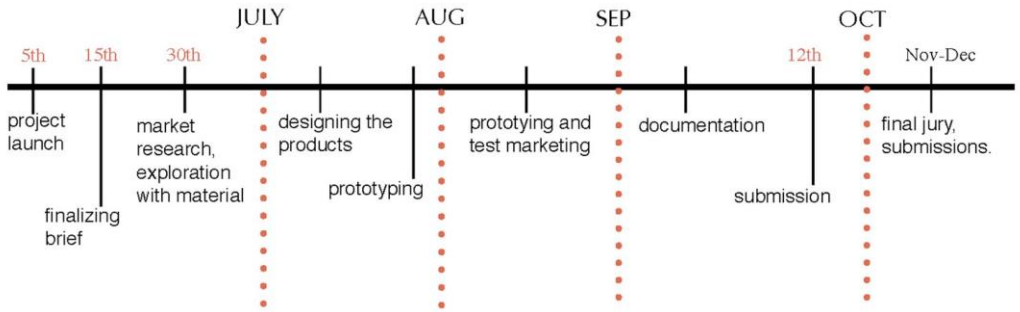
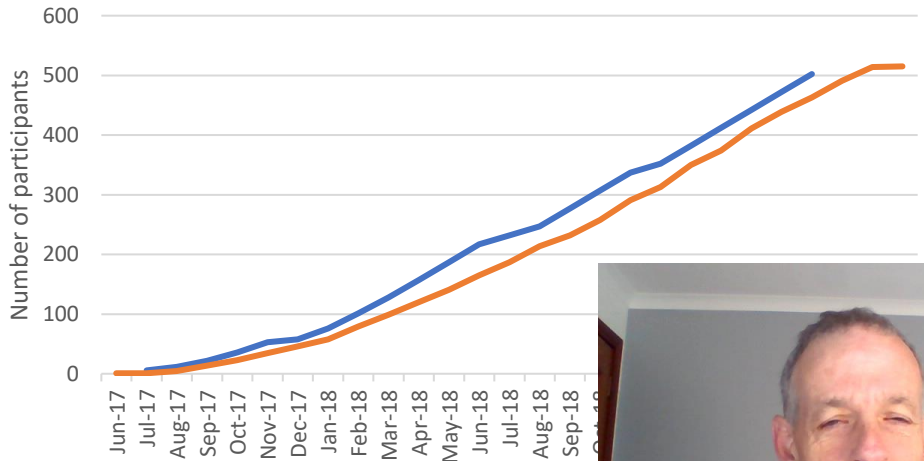
  - Most of work done (for me)
- Oct 16.  Funding decision




# Time lines

- Oct 16-May 17.  Convert plan into reality
  - Algorithm
  - Do centres really want to recruit
  - Quite a few forms
- Jun 17-Jul 20.  Recruit AND follow up
  - Weekly meetings
  - Apparatus
  - Juggling budget
  - Pandemic

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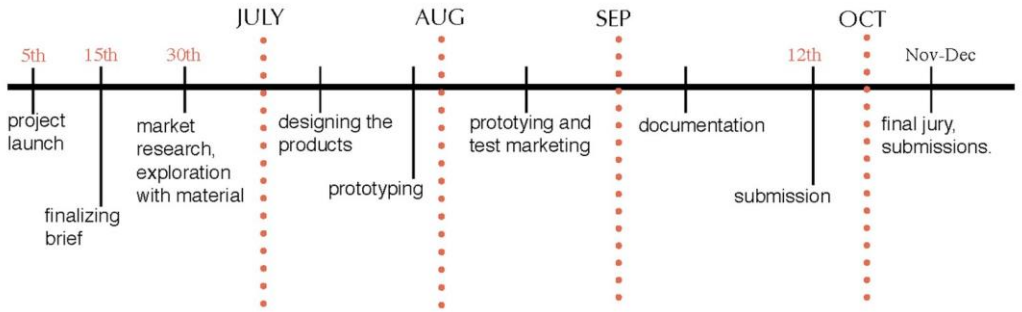
- Jan 22. Lancet RM
- Jun 22. Monograph




Articles

**Reducing asthma attacks in children using exhal oxide (RAACENO) as a biomarker to inform treat strategy: a multicentre, parallel, randomised, co phase 3 trial**

*Steve Turner, Seonaidh Cotton, Jessica Wood, Victoria Bell, Edwin-Amalraj Raja, Neil W Scott, Heather Morgan, Louis Charlotte Kennedy, Graham Scotland, Shona Fielding, Graeme MacLennan, John Norrie, Mark Forrest, Erol A Gaillard Marielle Pijnenburg, Mike Thomas, David Price*

# But you can’t win them all

- Use genetics to guide treatment
- HTA
- Dec ’17
- “Dear John” letter
  - Lack of important to the NHS
  - Outcome not meaningful
  - Not good value for money
- But informal congratulations!


# Third time lucky

So nitric oxide does not help

Might spirometry?

- Jul 19. Expression of interest
- May 20.  Full submission
- Aug 20.  Changes
- Oct 20.  Funding letter
- Oct 22.  Open for recruitment

# Reflections

A message to my 2015 self…..

- More time than I thought (>10%)
- More hurdles than I thought
- More rewarding/fun than I thought
- Made a difference
- Still time for one more application!


# This is the most important bit!

Team effort

- Most excellent trial team
- Co applicants
- Friends up and down the UK
- Sponsor, R&D, ethics
- Children and families
- Funder

# THANK YOU

## FAQ – TO BE COLLATED

Contact: Alan.McNair@gov.scot
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In the service of Scotland

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