

MRC

Medical
Research
Council

The EME Programme

NHS
National Institute for
Health Research

Efficacy and Mechanism Evaluation Programme

EME February Webinars 2018

The EME Programme

Today we are covering both researcher led and commissioned calls in this webinar.

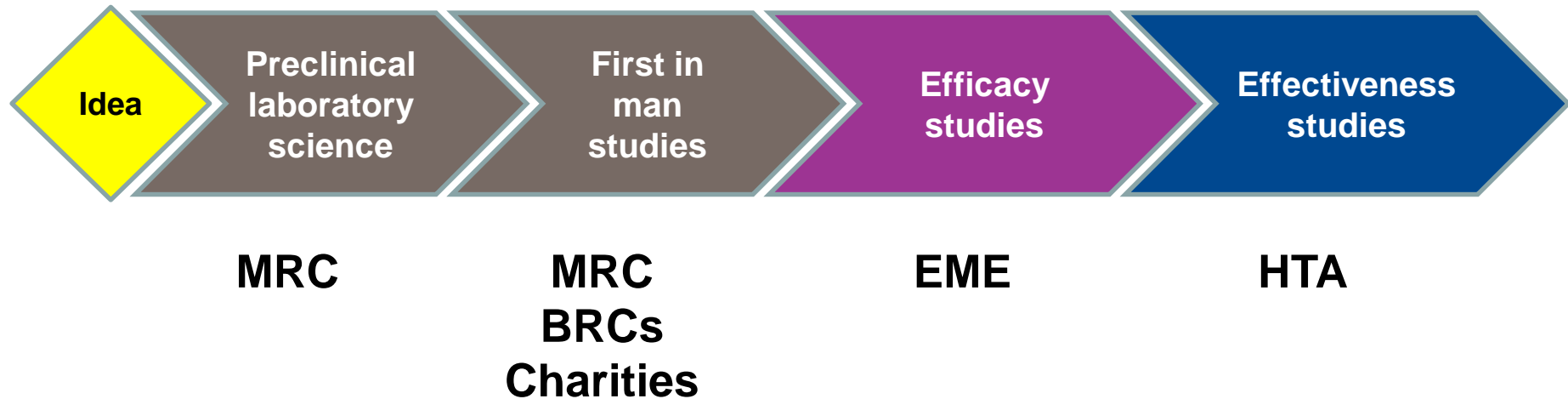
We will cover areas common to both, but will take specific questions on Commissioned calls in the Q&A session at the end.

The EME Programme

- Where EME fits into UK biomedical research funding
- What will EME fund?
- What won't EME fund?
- The EME Programme vision
- The application/funding process

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MRC/NIHR clinical research: the Managed Translational Pathway



The EME Programme

In simple terms:

MRC
Can it work?

*Discovery science and
“first in man”*

EME
Does it work?

Efficacy

HTA
Is it worth it?

Effectiveness

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What will EME support?

- 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.

Ways to increase “pull through” of studies

- 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 will EME not support?

- 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 programme vision

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

We are particularly interested in studies with:

- Patient stratification.
- Methodological innovation.
- Broader diversity of interventions.
- Novel use of information enabled by digital technology.

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The EME Programme

The application process

(with hints and tips on getting it right)

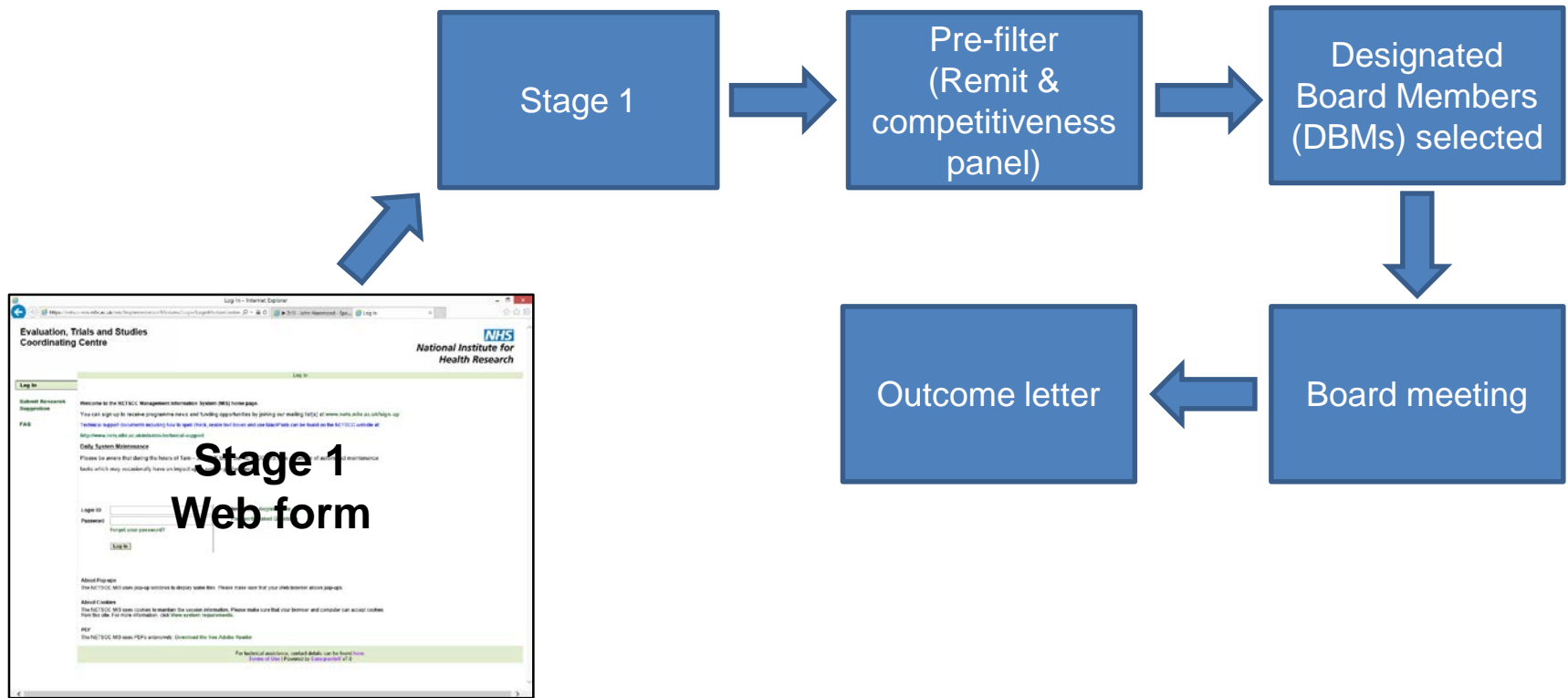
Funding applications:

- Can be a researcher's idea ("Researcher led").
- Can be in response to our call for research in a particular area ("Commissioned").
- Nearly always two stage (stage 1 and stage 2 applications).
 - Mechanisms of action of health interventions (1 stage with eligibility form)

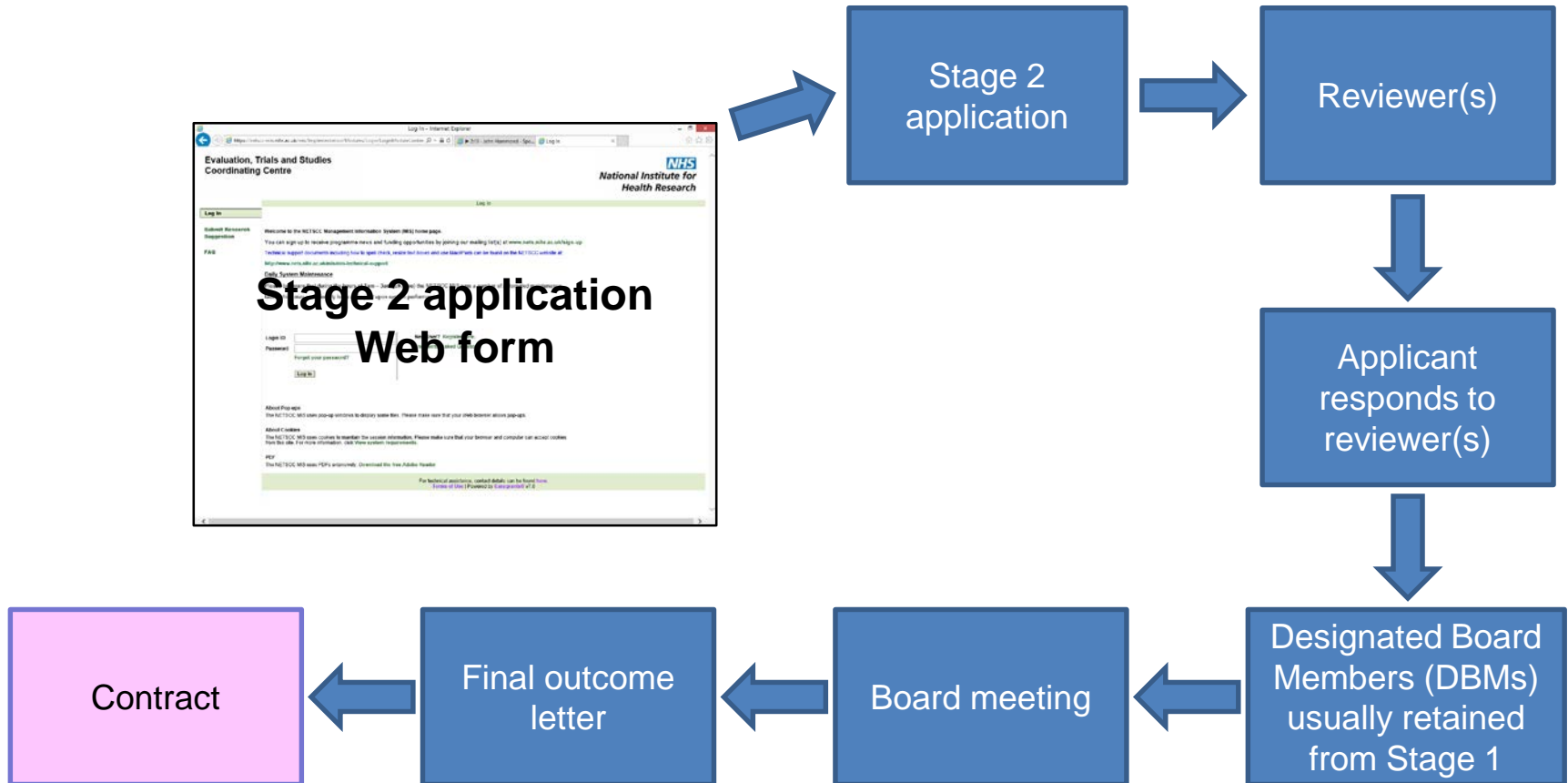
Current calls: (close date: 27 March 2018)

- Inherited myopathies and muscular dystrophies
- Osteoporosis
- Mechanisms of action of behavioural and psychological interventions to improve health
- Mental Health Themed Call
- Mechanisms of action of health interventions
- Highlight notice (researcher led) Complex Health and Care Needs in Older People
- Researcher led

Stage 1 (outline) application process



Stage 2 (full) application process



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.
 - 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

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?

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
 - Board Members

Contact details:

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Useful resources

<https://www.nihr.ac.uk/funding-and-support/funding-for-research-studies/funding-programmes/efficacy-and-mechanism-evaluation/>

Examples of proof of concept

<https://www.nihr.ac.uk/funding-and-support/documents/funding-for-research-studies/research-programmes/EME/how-does-eme-define-proof-of-concept.pdf>

Examples of mechanistic studies

<https://www.nihr.ac.uk/funding-and-support/documents/funding-for-research-studies/research-programmes/EME/how-does-eme-define-mechanistic-studies.pdf>