

The EME Programme

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Efficacy and Mechanism Evaluation Programme

**EME webinar
2017**

The EME Programme

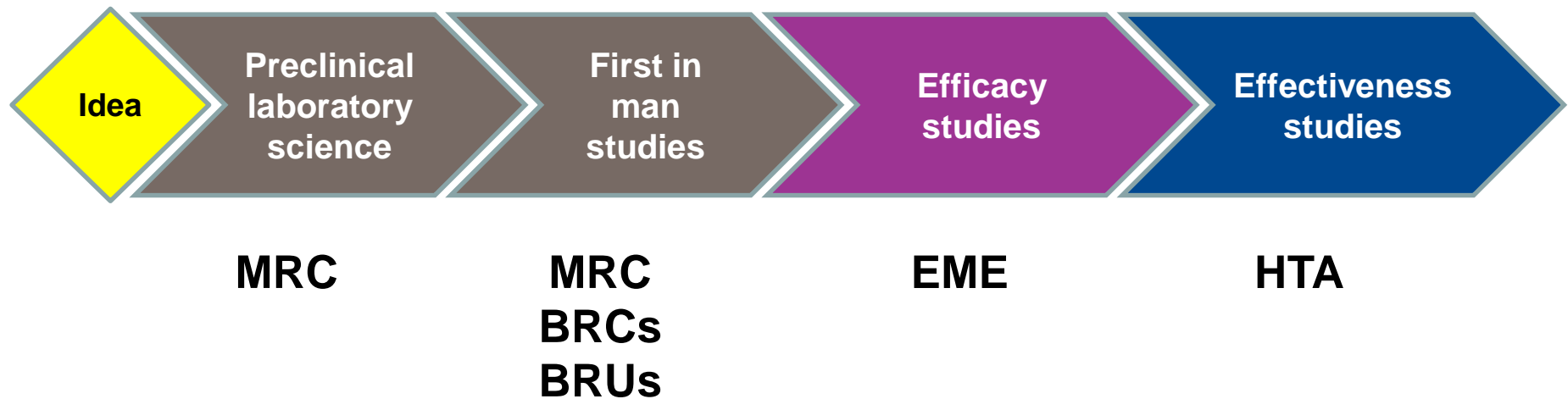
- Where EME fits into UK biomedical research funding
- What will EME fund?
- What won't EME fund?
- The EME Programme vision
- The application/funding process

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MRC/NIHR clinical research: the Managed Translational Pathway



The EME Programme



MRC/NIHR clinical research

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, increasing the knowledge that can be gained

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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.

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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

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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 Efficacy and Mechanism Evaluation Programme (EME):

The Application Process
&
Hints & Tips for Getting it Right

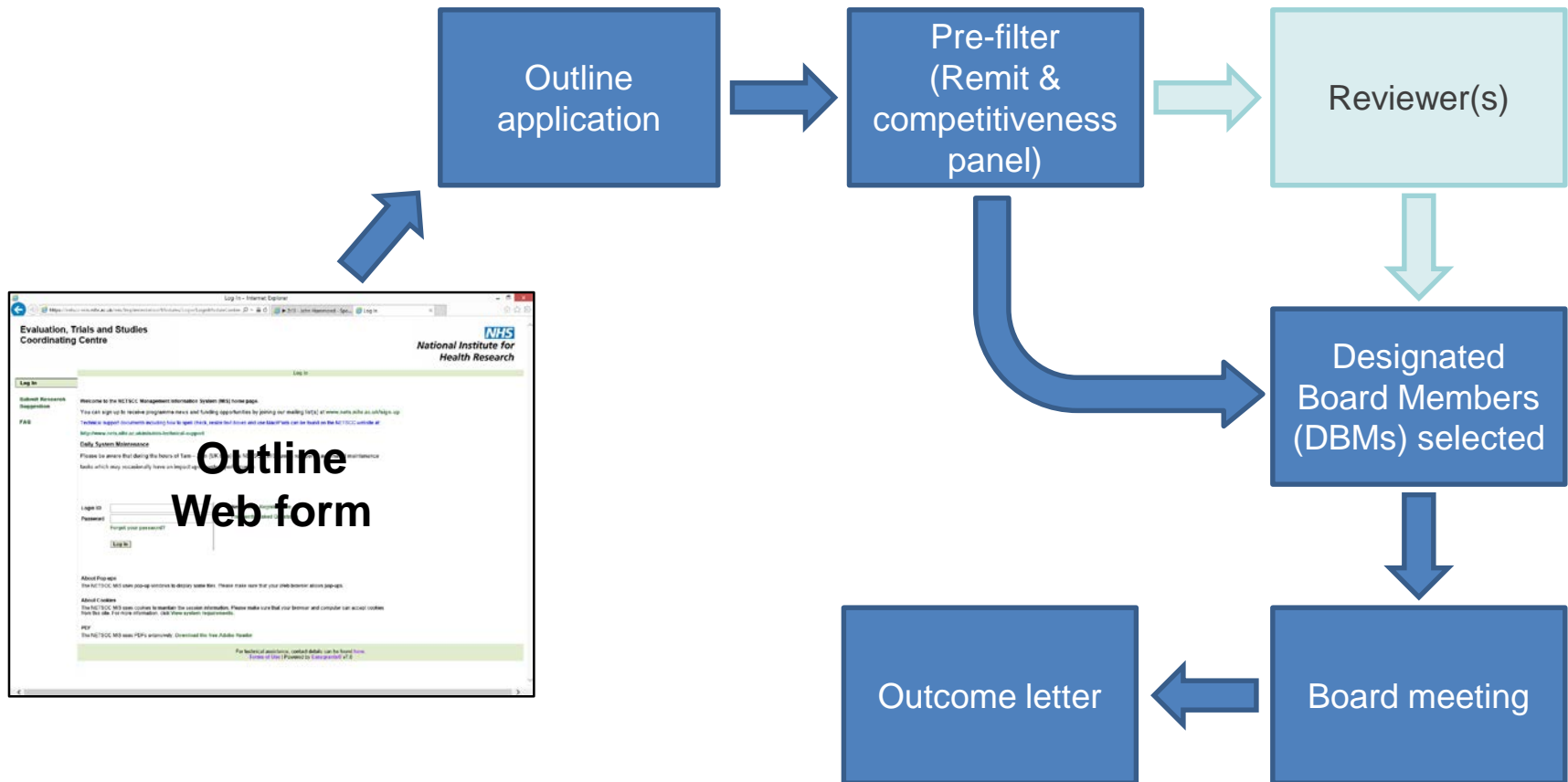
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Funding applications:

- 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 (outline and full applications)

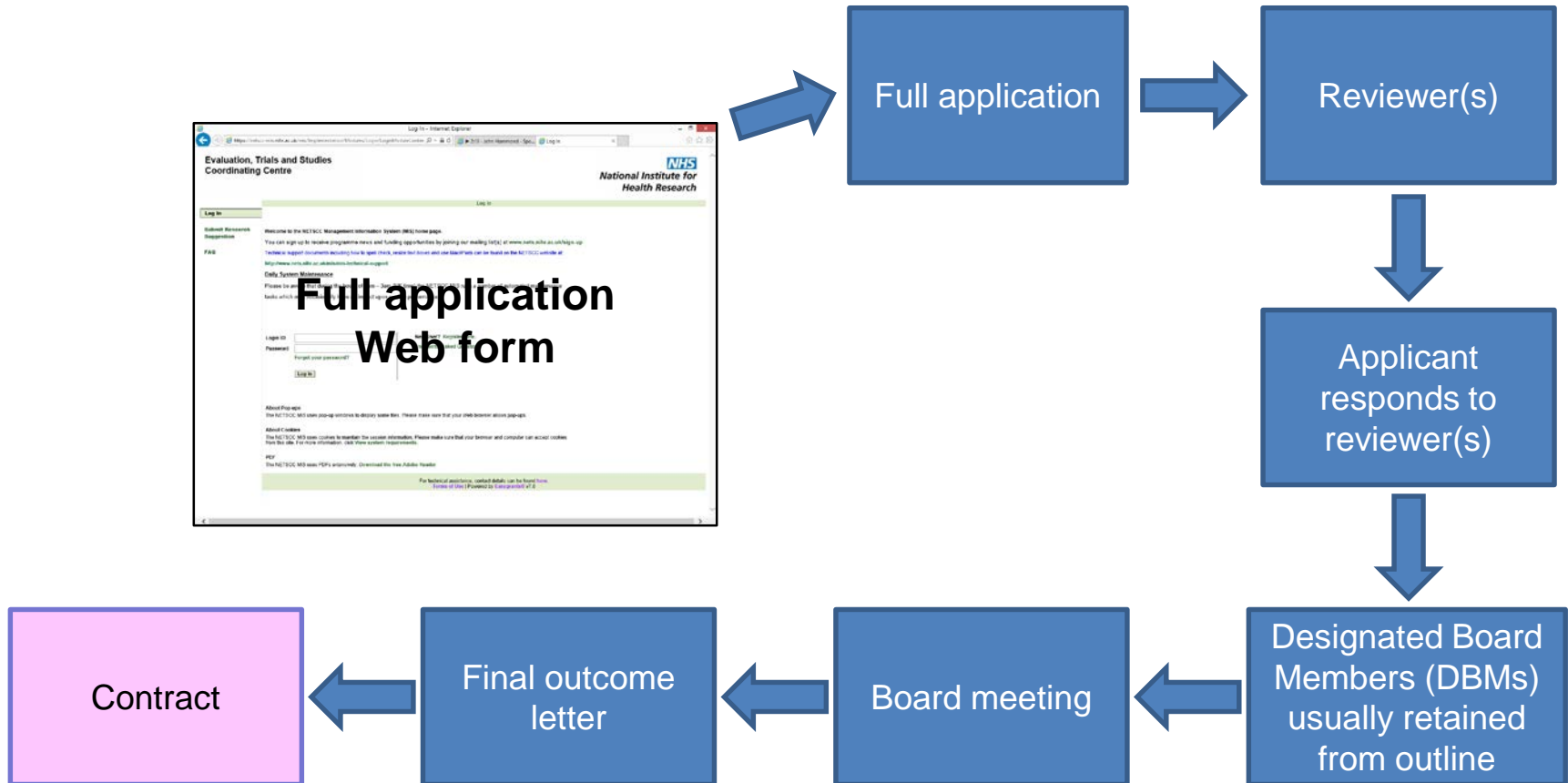
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Outline application process



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Full application process



Key Considerations

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 dosage and any side effects of the intervention

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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

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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?

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Research Dissemination & 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?

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Feedback

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

Contact details:

Direct email	Telephone number
eme@nihr.ac.uk	+44 (0)23 8059 4303

Useful resources

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

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Any Questions?