

FAQ: Would my primary research idea be of interest to the EME programme or the HTA programme?

EME Research

The Efficacy and Mechanism Evaluation (EME) programme supports research that is designed to advance scientific knowledge. EME research is undertaken earlier in the development pathway than HTA research and is undertaken when there is some initial evidence that the technology is efficacious in patients (where proof of concept in humans has already been achieved) but a study is needed to determine definitive proof of clinical efficacy, size of effect, safety and possibly effectiveness. An intervention which is being tested for efficacy must be clearly present in all evaluations, other than diagnostic evaluations.

HTA Research

The Health Technology Assessment (HTA) programme supports research that is immediately useful to clinical practice and policy/decision makers. HTA research is undertaken when there is evidence to show the technology is efficacious but there is uncertainty around its clinical and cost effectiveness in a real life NHS setting in comparison to the current best alternative(s). There may also be uncertainty around its place in the existing care pathway.

Table comparing typical characteristics of HTA and EME research:

Characteristic	EME	HTA
Evaluates	Efficacy, safety and possibly effectiveness of a medical intervention under ideal conditions	Effectiveness of a medical intervention in a real life NHS setting
Types of research	Primary (clinical research) Usually exploratory research with expert care	Primary (clinical research) Secondary (evidence synthesis, e.g. a systematic review or meta analysis) Usually pragmatic research with routine care
Stages of research	EME would consider research which has already been successful in the first stages of testing in humans (often volunteers), and where the required intensity/level/dose of an intervention has been decided EME research would be specifically designed to evaluate efficacy and whether the treatment works under ideal conditions, and may gather further information on safety	HTA research would normally follow that which is suited to the EME programme, however there is some overlap with the later stages of EME research The main focus of HTA research is long-term effectiveness and the impact on patients' quality of life as well as cost effectiveness. These studies would evaluate effectiveness in a real-world NHS setting
Design	A clinical trial or evaluative study (not necessarily an RCT). May also include laboratory based, or similar studies that are embedded within the main EME study	Often a pragmatic randomised controlled trial although other study designs may be used for instance in the evaluation of diagnostic tests
Participant eligibility criteria	More stringent and not necessarily representative of the UK population	Wide and representative of the UK population and reflects the mix of patients likely to be seen in normal clinical practice

Characteristic	EME	HTA
No. of participants & centres	Small to Large - may be single or multi-centre	Generally large – adequate to assess minimally important differences from a patient perspective; usually multi-centre generating results that are generalisable to the NHS
Technology*	Mostly developed and defined but some refinement / fine tuning may still be needed	Fully defined and developed technology
Comparator	Likely to be placebo but could be usual care or the best active alternative	The best active alternative or usual care. Placebos may be used in conjunction with best treatment to blind trial participants
Outcomes	Validated surrogate markers as indicators of health outcome are acceptable	Clinically important outcomes that matter to patients and that measure health gain
Follow up	Sufficient for the outcome to be manifest. When surrogate outcomes are used, for example, this may be shorter than in typical HTA research	Sufficient to ensure that a wider range of effects are identified other than those which are evident immediately after treatment
Health economic component included?	Not usually	Usually cost-utility or cost effectiveness
Can a mechanistic evaluation be included as part of the main study?	Yes. Evaluations which help to understand how an intervention works, or how behaviour affects or is affected by an intervention, may be included as part of the main EME study	Not usually, it would only be a secondary consideration to assessing cost-effectiveness
Diagnostic evaluations	Likely to support validation of a diagnostic test Unlikely to include evaluations which seek to determine the effects of introducing a new diagnostic test into clinical practice	Unlikely to support evaluations which seek to determine the normal range of values for a diagnostic test through observational studies in healthy people Likely to support the evaluation of cost effectiveness in routine clinical practice

*By “technology” we mean any method used to promote health, prevent and treat disease and improve rehabilitation or long-term care. “Technologies” in this context are not confined to new drugs but include procedures, devices, tests, settings of care, screening programmes and any intervention used in the treatment, prevention or diagnosis of disease.

A key difference between an EME and an HTA study is whether the study can be broadly categorised as either an explanatory or a pragmatic study. Explanatory (or efficacy) studies test interventions under ideal conditions and describe studies that test causal research hypotheses; and Pragmatic (or effectiveness) studies test interventions under usual conditions, and describe studies that help users choose between options for care [Thorpe et al, Journal of Clinical Epidemiology, 2009, Volume 62, Issue 5, Pages 464-465](#), have published the PRECIS tool to assist in understanding these differences and helping in trial design; whilst HTA prioritisation and commissioning boards do not explicitly apply this tool in decision making, it is a useful reference source in preparing your application.

For further information please see:
 The EME remit www.eme.ac.uk
 and the HTA remit www.hta.ac.uk