Identifying the appropriate funding source for your clinical study or trial

MRC and NIHR work in collaboration to provide a spectrum of funding opportunities for clinical studies and trials. The following information is designed to help applicants identify the most appropriate funding scheme for their proposed clinical study.

Experimental Medicine Panel Research

The Experimental Medicine Panel aims to support interventional studies in humans, which are designed to further our understanding of the cause, progression and treatment of human disease. The Panel has a wide remit in terms of disease area and intervention modality, however all studies must involve an experimental intervention, or challenge, and be focussed on validating a mechanistic hypothesis.

DPFS Research

Developmental Pathway Funding Scheme (DPFS) aims to drive fundamental discoveries along the developmental pathway towards patient benefit and or commercialisation. It has a wide remit, providing support for projects from prototype development, pre-clinical refinement, evaluation, and safety and regulatory assessment through to clinical refinement and early phase clinical studies and trials (up to and including phase IIa). *The information in the table below focuses on the clinical aspects of the DPFS remit.*

EME Research

The Efficacy and Mechanism Evaluation (EME) Programme funds ambitious studies evaluating interventions that have the potential to make a step-change in the promotion of health, treatment of disease and improvement of rehabilitation or long-term care. The EME Programme supports clinical studies 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 large-scale study is needed to determine definitive proof of clinical efficacy and safety and which addresses mechanistic questions.

The EME Programme looks to attract studies with novel methodological designs that deliver results more efficiently, reduce the study timeline, and maximise the knowledge gained. The translational research it supports covers a wide range of new and repurposed interventions, such as diagnostic or prognostic tests and decision-making tools, therapeutics or behavioural treatments, medical devices, and public health initiatives delivered in the NHS.

HTA Research

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. 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 the typical characteristics of clinical studies and trials funded by the Experimental Medicine Panel, DPFS, EME and HTA:

Characteristic	Experimental Medicine Panel	DPFS	EME	HTA
Stage of research	The Experimental Medicine Panel supports interventional projects in humans designed to address mechanistic questions, utilising tools or challenges with established safety profiles. Supported projects will aim to produce new mechanistic insights and target validation. Outcomes will have the potential to enable the development of new therapeutic or diagnostic approaches in the future, and opportunities for “reverse translation” to discovery science.	In terms of studies in humans, DPFS supports early stage clinical studies and trials up to and including safety and early efficacy read out (phase IIa).	EME supports studies that start where the required intensity/level/dose of an intervention has been defined and there is already evidence of ‘proof of concept’ in humans i.e. signal of treatment effect. How much prior evidence of potential efficacy is needed will vary with the size of the translational step, the scale of the proposed study and the nature of the intervention. EME studies will determine definitive proof of clinical efficacy, size of effect, an indication of effectiveness, and/or test mechanism of action of intervention hypotheses.	HTA supports studies that start where some evidence of effectiveness of an intervention already exists and there is a need to compare with a current standard of care intervention, to determine which works best.

Evaluates	Studies should focus on validating a mechanistic hypothesis in humans through the use of a challenge or intervention.	Studies undertaken in humans should focus on establishing safety and proof of concept. The principal focus of the study should not be to understand disease mechanisms.	EME funded studies should 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.	Studies should evaluate the clinical and cost-effectiveness of a therapeutic intervention or diagnostic test, measured with outcomes that are important to patients.
Design	Studies to be conducted in humans with a focus on mechanistic primary outcomes. Studies must include an intervention or challenge. All forms of intervention which challenge the human system will be considered including pharmacological, immunological, physiological, psychological and infectious strategies. May include a small element of *in vitro* or *in vivo* preclinical studies (specifically to inform the proposed work in humans) but should not be the main focus.	In terms of studies in humans, these can be early phase clinical trials (up to and including phase IIa). Studies would generally aim to evaluate the intervention in controlled conditions. The development of the intervention may still require some refinement. Studies to be designed to ensure that outcomes meet the regulators' needs for downstream development.	Studies to be clinical trials, and other robustly designed studies (not necessarily an RCT), that test the efficacy and/or mechanisms of interventions. Innovative study designs involving stratification, the use of routinely collected digital data or novel methodologies are strongly encouraged, where appropriate and likely to enhance the efficiency of the trial.	Studies to be systematic reviews, economic modelling, meta-analyses, randomised trials, non-randomised trials and a number of other study designs which offer the opportunity to reduce uncertainty around best clinical practice. Phase 2 trials, feasibility and pilot studies are not supported unless directly commissioned.

Participant eligibility criteria	Relevant patient groups or healthy volunteers.	Relevant patient groups or healthy volunteers.	Well-defined, or homogenous, population of relevant patient group(s).	Entry and inclusion criteria should reflect health and social care practice and follow health and social care needs so that the results can be widely applicable.
Lead Investigator	In addition to standard MRC PI eligibility criteria, the Experimental Medicine Panel also supports applications from junior investigators; those in receipt of fellowships (e.g.MRC, National Institute for Health Research (NIHR), charity, learned societies) and NIHR lectureships are eligible, if their fellowship terms and conditions allow.	The PI for DPFS applications should fit the standard MRC eligibility criteria.	EME supports applications from early career investigators as study CI. However, evidence of support for CI from an experienced team is required.	HTA supports applications from mid-career researchers as study CI. However, evidence of support for CI from an experienced co-Chief Investigator and or an experienced team is required.
Technology	Drugs, interventions or measures with established safety profiles applied in new settings or conditions to probe disease or therapeutic mechanisms. The validation of novel readouts and technologies will also be considered.	A new intervention (or a new indication for an existing intervention) which requires proof of principle or safety in humans. All forms of intervention will be considered, for example drug, biologic or cell-based treatments, vaccines, devices, diagnostics, surgical tools or techniques, behavioural and psychological interventions, digital healthcare, radiotherapy and radiation approaches, and novel applications of existing therapeutics.	"Technologies" in this context are not confined to new drugs but include procedures, devices, tests, settings of care, screening programmes and any intervention to promote health, diagnose, prevent and treat disease and improve rehabilitation or long-term care. Novel or repurposed interventions and technologies. Typically technologies are fully developed/defined. However, some refinement may be needed (to a value of 25% of the proposed project cost).	"Technologies" in this context are not confined to new drugs but include procedures, devices, tests, settings of care, screening programmes and any intervention to promote health, diagnose, prevent and treat disease and improve rehabilitation or long-term care. Technologies should be fully defined and developed ready to use in NHS and social care practice.

Outcome measures	Studies will primarily have mechanistic insight outcomes but may also provide initial, human proof of concept evidence through secondary or exploratory outcomes.	Studies conducted in humans will demonstrate proof of concept and may include surrogate outcome measures of efficacy, and measures of safety. The research will provide supporting data for the next stage of development, including a large-scale evaluative trial.	Studies will use clinical or well-validated surrogate outcomes. Studies that validate potential surrogate outcomes against a primary clinical outcome, within the main clinical trial can also be considered.	Studies will have outcome measures that are important to patients and reflect their experience of health and care gain.
Animal studies	A small element of *in vivo* preclinical work will be supported if informed by or informing the work in humans but the main focus should be on human participants.	Animal studies, including pre-clinical refinement, evaluation, and safety and regulatory assessment are within the remit of DPFS.	Research involving animals is not supported	Research involving animals is not supported
Can a mechanistic evaluation be included as part of the main study?	Yes. The principal focus of the study should be to explore disease mechanisms or mechanisms of action of interventions with established safety profiles.	The principal focus of the clinical study should not be to understand the aetiology or mechanisms of disease. However, opportunistic mechanistic work that informs stratification approaches or the design of future, larger-scale clinical trials is permissible. In order to be supported by the Panel, this work should be carefully designed, provide value for money and not compromise the deliverability of the main study.	Studies can evaluate an intervention's efficacy and test hypotheses around its mechanism of action	Where a strong case is made, the HTA Programme will fund collection of blood samples or other biomarkers, but will not fund the storage or analysis of these samples. Hypothesis testing mechanistic studies utilising patients, data and samples of current or completed HTA studies can be supported via the EME programme.

Diagnostic development, validation and evaluations	Likely to support projects with the future aim of developing and refining diagnostic and companion diagnostic devices through greater understanding of disease mechanisms. Likely to support the validation of novel readouts/technologies, particularly in the context of early evaluation of clinical efficacy.	DPFS is likely to support early test development and analytical validation, in addition to retrospective and prospective clinical validation. DPFS is unlikely to support late stage clinical validation or test evaluation.	Studies can validate accuracy; diagnostic or prognostic value. Clinical utility evaluations seeking to determine the effects of introducing a new diagnostic test into clinical practice will not be supported.	Likely to support diagnostic test accuracy studies or trials comparing treatment pathways including a diagnostic test with a relevant comparator. Studies can also evaluate cost effectiveness in routine 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.
Working in partnership	Applications including partnerships with charities or industry are encouraged where these add value to the project, for example in terms of access to expertise, technologies, reagents or funding. Please note that industrial collaboration is not a prerequisite for application. Industry led applications are not supported.	Applications including partnerships with charities or industry are encouraged where these add value to the project, for example in terms of access to expertise, technologies, reagents or funding. Please note that industrial collaboration is not a prerequisite for application. Industry led applications are not supported.	All applications should include at least two of the following partners; industry, academia, and the NHS. Industry may apply as a study lead applicant or co-applicant Collaboration with small and medium enterprises is encouraged. Charity partnerships are welcome. All co-funding arrangements must be discussed with the EME programme. All collaboration arrangements must abide by terms of NIHR research funding.	All applications should include at least two of the following partners; industry, academia, and the NHS. Industry may apply as a study lead applicant or co-applicant. Collaboration with small and medium enterprises is encouraged. Charity partnerships are welcome. All co-funding arrangements must be discussed with the HTA programme. All collaboration arrangements must abide by terms of NIHR research funding.