

19/49 CALL FOR AMBITIOUS DATA-ENABLED TRIALS, HEALTH SERVICES AND PUBLIC HEALTH RESEARCH STUDIES

SUMMARY

The HTA, HS&DR and PHR programmes are interested in funding studies using innovative data-enabled designs to answer pressing knowledge gaps for health, public health and, or social care evidence users, NHS patients, people with lived experience and, or policy-makers.

Applicants need to demonstrate first and foremost that the proposed work addresses an identified and important health-related research question which, if answered will make a difference to practice and health, improve the lives of populations or service users, and, or support evidence-informed decision-making. In their proposal applicants will need to demonstrate to the programmes that simply exploring how routine data *can* be used is not the primary purpose of a proposed piece of work.

The programmes are particularly interested in ambitious studies that use data-enabled approaches at scale. Applicants should note the programmes are also interested in proposals that include participants or populations who would not normally be engaged with research due to their location or socio-demographic characteristics; the programmes wish to contribute to addressing health inequalities through engagement in research and bring research to areas of the country of most patient or population need. However, the programmes are looking for scale first and foremost.

Despite the potential challenges of doing this sort of research, the programmes will be looking to ensure that research proposals are engineered as simply as possible, and researchers are asked to demonstrate this in their application. The programmes wish to emphasise that proposals need to be efficient – by efficient we mean at less cost, as well as being usually faster and larger than equivalent clinical trials or other studies using traditional approaches, in order to be rigorous and impactful. Applicants will therefore need to explain how their proposed study will deliver robust answers using streamlined approaches.

In addition to large scale studies, this call is eligible for small pilot studies up to the value of £10k, which should be embedded in the main study. These pilots would contribute to shared learning, and in future might be harnessed by Health Data Research UK ([HDR UK](#)). Pilot studies should evaluate essential methodological elements of the proposed work such as:

- i) Sufficient accuracy of identification of participants in the required cohort(s) in diagnosis, location or service pathway

- ii) How accurate do the data need to be to provide reliable answers?
- iii) How to achieve interoperability or how to cope with this issue
- iv) Using different technologies to carry out study assessments
- v) Novel methods using linkage of routine data sets, from within or outside the health sector
- vi) Novel methods for data acquisition using data science

Applicants will have to demonstrate an intention to ensure longevity of data collection methods and its adaptability beyond the immediate context of the trial or study. The programmes are also interested in proposals which build on existing algorithms and data linkage solutions. Applicants need to explain what the risks might be to delivering the study as proposed, and how these risks might be mitigated – this could include issues of timeliness of data access. The programmes will want to understand how applicants will work with regulators and legislative frameworks, such as GDPR

Applicants are reminded that the expertise required to deliver the type of trial or study for this call is likely to be different, at least in part, from the more usual project and trial management approach. The make-up and expertise of the team will need to be credible and proportionate from the outset of the application process.

Given the scope of this call, we expect to receive applications from co-ordinated multidisciplinary teams of investigators spanning both health and non-health specialties/disciplines, bringing together all the necessary skills and expertise required to deliver the research proposed.

We would welcome applications that span the remit of more than one of the participating research programmes (HTA, HS&DR and PHR), whilst also accepting applications in remit for just one programme.

Deadline for proposals:

The deadline for stage 1 applications is **4 September 2019**.

For support developing applications, applicants are also encouraged to contact their local NIHR Research Design Service (RDS) or equivalent in the first instance.

Applicants who would like advice on whether their research proposal is likely to be in the remit of the call should contact crossprogramme@nihr.ac.uk

SUPPORTING INFORMATION

In October 2018, the National Institute for Health Research (NIHR), Health Data Research UK (HDRUK) and Clinical Practice Research Datalink (CPRD) held a roundtable to discuss the issues of running data-enabled randomised clinical trials.

The roundtable heard from various investigators who had used this data-enabled approach in their work.

The studies showcased are listed below:

Jennifer Quint: [The COPE COPD study](#)

John Wilding: [A Pragmatic Trial to Evaluate the Comparative Effectiveness Between Dapagliflozin and Standard of Care in Type 2 Diabetes Patients \(DECIDE Study\) \(DECIDE\)](#)

Louise Bowman: [ASCEND \(A Study of Cardiovascular Events in Diabetes\)](#)

Martin Gibson: [Salford Lung Study](#)

Martin Gulliford: [Electronically-delivered, multi-component interventions to reduce unnecessary antibiotic prescribing in primary care. A cluster randomised trial using electronic health records \(eCRT2\)](#)

Liam Smeeth: [StatinWISE](#)

Martin Landray: [REVEAL trial](#)

Contributions were also made by:

Paula Williamson, University of Liverpool and director of the North West Hub for Trials Methodology Research ([MRC Network of Hubs for Trial Methodology Research](#))

Janet Valentine from the [CPRD](#)

Andrew Morris from the [HDRUK](#)

Tom Denwood from [NHS Digital](#)

We have permission to provide the presentations from that day and these are available in the links below:

Jennifer Quint: [The COPE COPD study](#)

John Wilding: [DECIDE Study](#)

Louise Bowman: [ASCEND](#)

Martin Gibson: [Salford Lung Study](#)

Martin Gulliford: [Electronically-delivered, multi-component interventions to reduce unnecessary antibiotic prescribing in primary care. A cluster randomised trial using electronic health records \(eCRT2\)](#)

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How to apply & supporting information:

The programmes involved in this call are:

- [Health Services and Delivery Research \(HS&DR\)](#)
- [Health Technology Assessment \(HTA\)](#)
- [Public Health Research programme \(PHR\)](#)

Applicants should note:

- Proposals must be within the remit of at least one participating NIHR Programme. However, we expect to receive applications which span the remit of one or more programme. To enable applications to be written without concern for individual programme remits or boundaries, applications will be submitted to one cross programme team, rather than to individual programmes.
- Patient and public involvement should be included within the application and study design.
- All the participating programmes are interested in economic elements which are likely to make the research even more relevant for commissioners of health and social care services.
- The existing NIHR portfolio of [published](#) and [funded](#) projects avoid duplication of research (this is especially important when justifying the need for the proposed research question).
- The current programme [funding opportunities](#) and potential research topics underdevelopment.
- That after the initial call close dates, the participating programmes will continue to be interested in receiving research proposals which are data-enabled in order to answer important research questions for health and social care evidence users.

Participating Programme remits:

HS&DR Programme:

The HS&DR Programme funds research to produce evidence on the quality, accessibility and organisation of health and social care services. Robust mixed methods studies which are data-enabled, are invited to answer questions in the programme's remit. Examples of HS&DR-funded studies using complex data-driven methods are provided at **Appendix 1**. All can be viewed on the NIHR website at

<https://www.journalslibrary.nihr.ac.uk/programmes/hta/>

HTA Programme:

For the purposes of this call, the programme is interested in data-enabled clinical trial designs only. The HTA programme is hoping to attract ambitious data-enabled trial proposals (or “e-trials”) that can use routine data sources for key trial processes such as patient identification, intervention delivery and for collecting outcomes in an efficient way. By efficient we mean at lower cost and possibly faster than traditional trial approaches. Proposed interventions need to be mature enough to be tested on a national scale. In 2014 the HTA programme put out a call for trials using efficient study designs. A list of studies funded under that call is provided in **Appendix 2**. All can be viewed on the NIHR website at <https://www.journalslibrary.nihr.ac.uk/programmes/hta/>

PHR Programme:

The PHR Programme evaluates non-NHS public health interventions intended to improve the health of the public and reduce inequalities in health. The programme is keen to consider proposals that operate at a population level and which will inform public health decision-makers in the UK. We are interested in scalable interventions to promote good health or prevent ill health across the life-course. We are also interested in population interventions aimed at reducing the impact of poor health and/or the health inequalities characteristic of health issues. Where justified, proposals may focus on populations that are defined by social determinants, rather than by disease.

The programme is interested in the use of data from a wide range of sources and sectors, not just health, and how they can be explored, combined and analysed to explore health related outcomes.

In 2013, the PHR programme put out a call for studies using pre-existing data. A list of studies funded under this call are provided in **Appendix 3**. All can be viewed on the NIHR website at <https://www.journalslibrary.nihr.ac.uk/programmes/phr/>

Appendix 1: HS&DR portfolio examples

Chief Investigator	Title
Glasby, Jon	A comprehensive profile and comparative analysis of the characteristics, patient experience and community value of the 'classic' community hospital situated in contrasting contexts and communities
Jacobs, Rowena	Does better quality of primary care influence admissions and health outcomes for people with serious mental illness (SMI)? A linked patient-level analysis of the full patient care pathway
Judge, Andrew	Models of care for the delivery of secondary fracture prevention after hip fracture: a health service cost, clinical outcomes and cost-effectiveness study within the South Central Region.
Pitt, Martin	NeoNet: The right cot, at the right time, at the right place 2. Providing a national demand/capacity model for neonatal care in England
Tsang, Victor	Selection, definition and evaluation of important early morbidities associated with paediatric cardiac surgery
Gulliford, Martin	Safety of reducing antibiotic prescribing in primary care. New evidence from electronic health records

Appendix 2: HTA efficient studies call portfolio

Chief Investigator	Title
Hiemstra, Thomas	Survival Improvement with Cholecalciferol in Patients on Dialysis – the SIMPLIFIED registry trial
Vaidya, Jayant	Extended follow up of the TARGIT-A trial
Torgerson, David	Does Occupational Therapist led environmental assessment and modification reduce falls among high risk older people?
Roffe, Christine	The Metoclopramide and selective oral decontamination for Avoiding Pneumonia after Stroke (MAPS-2) Trial: a 2x2 double-blind, randomized controlled trial of metoclopramide and selective oral decontamination for the prevention of pneumonia in patients with dysphagia after an acute stroke
Smeeth, Liam	Statin Web-based Investigation of Side Effects Trial (Statin WISE Trial)
Lobban, Fiona	An online randomised controlled trial to evaluate the clinical and cost effectiveness of a peer supported self-management intervention for relatives of people with psychosis or bipolar disorder: Relatives Education And Coping Toolkit (REACT)
Preiss, David	A randomised placebo-controlled clinical trial of fenofibrate to prevent progression of non-proliferative retinopathy in diabetes (LENS: Lowering Events in Non-proliferative retinopathy in Scotland)
Davies, Neil	What is the effectiveness of varenicline compared with nicotine replacement therapy for long term smoking cessation and clinically important outcomes such as mortality, myocardial infarction and frequency of service use? Evidence from the Clinical Practice Research Datalink
(will be Amanda Cross)	Retrospective cohort study to examine the long-term colorectal cancer risk and surveillance requirements following diagnosis of adenomas (The All Adenomas Study)
Rai, Dheeraj	Antidepressant use during pregnancy: assessing benefits to mothers and long-term neurodevelopmental risks to children using the Clinical Practice Research Datalink

Douglas, Ian	Real World Effects of Medications for Chronic Obstructive Pulmonary Disease
Taylor, Rod	Exercise-based rehabilitation for chronic heart failure (ExTraMATCH II): An individual participant data meta-analysis of randomised controlled trials
Mouncey, Paul	Evaluating the clinical and cost effectiveness of using a more conservative mean arterial pressure target range to guide careful titration of vasopressors to minimise dose and duration in older critically ill patients with vasodilatory hypotension: the 65 trial.
Prieto-Alhambra, Daniel	Risk-benefit and costs of unicompartmental (compared to total) knee replacement for patients with multiple co-morbidities: a non-randomised study, and different novel approaches to minimise confounding.
Caskey, Fergus	The High-volume Haemodiafiltration vs High-flux Haemodialysis Registry Trial (H4RT)
Edwards, Mark	FLO-ELA: FLuid Optimisation in Emergency LAParotomy. Open, multi-centre, randomised controlled trial of cardiac output-guided haemodynamic therapy compared to usual care in patients undergoing emergency bowel surgery
Blair, Peter	A clinical effectiveness investigation of a multi-faceted intervention (incorporating a prognostic algorithm) to improve management of antibiotics for CHildren presenting to primary care with acute COugh and respiratory tract infection (CHICO): an efficient cluster RCT informed by a feasibility RCT
Southern, Kevin	The cystic fibrosis (CF) anti-staphylococcal antibiotic prophylaxis trial (CF START); a randomised registry trial to assess the safety and efficacy of flucloxacillin as a longterm prophylaxis agent for infants with CF

Appendix 3: PHR portfolio examples

Chief Investigator	Title
Platt, Lucy	Assessing the impact and cost-effectiveness of needle/syringe provision on hepatitis C transmission among people who inject drugs: an analysis of pooled datasets and economic modelling
Gardner, Frances	How far could widespread dissemination of parenting programmes improve child antisocial behaviour and reduce social inequalities? Combining datasets from trials in different communities to establish for whom programmes are effective and cost effective
Leyland, Alistair	Evaluation of Health in Pregnancy Grants in Scotland
Dundas, Ruth	Evaluation of the Healthy Start Voucher Scheme in UK: a natural experiment using the Growing Up in Scotland record linkage study and the Infant Feeding Survey
Rodgers, Sarah	Health impact, and economic value, of meeting housing quality standards: a retrospective longitudinal data linkage study
Gardeners, Frances	Could scale-up of parenting programmes improve child disruptive behaviour and reduce social inequalities? Using individual participant data meta-analysis to establish for whom programmes are effective and cost-effective
Robling, Michael	Evaluating the long-term effectiveness, and the cost and consequences of the Family Nurse Partnership parenting support programme in reducing maltreatment in young children
Fone, David	Change in alcohol outlet density and alcohol-related harm to population health
Wilkinson, Paul	The impact of home energy efficiency interventions and winter fuel payments on winter and cold-related mortality and morbidity in England: evaluation of a natural experiment