

Priorities in Clinical Research 2019

Research Awards

Summary

We are Versus Arthritis. We're the 10 million people living with arthritis. We're the carers, researchers, healthcare professionals, friends, patients, runners and fundraisers all united in our ambition to ensure that one day, no one will have to live with the pain, fatigue and isolation that arthritis causes.

For far too long, arthritis has been viewed as something that is inevitable, insignificant and untreatable; shrugged off as 'just a bit of arthritis'. At Versus Arthritis we strive to do more and to be more ambitious in everything we do, working with and for people with arthritis. We are doing this by providing support, campaigning for the appropriate recognition for arthritis and funding and supporting research into discovery science, clinical trials and applied health services research.

Applications are invited to our Treatment subcommittee for clinical research funding seeking to address a question in a priority area defined in the strategies put forward by our previous [Clinical Studies Groups](#), those of [RheumaMap](#), the priorities set by the NIHR's James Lind Priority Setting Partnerships, where they are relevant to Versus Arthritis: [Hip and Knee Replacement for osteoarthritis](#), [Early Hip and Knee Osteoarthritis](#), [Surgery for Common Shoulder Problems](#), [Common Conditions Affecting the Hand and Wrist](#) and also the relevant research priority areas highlighted in the results of the recent 'Identifying Research Priorities for Elective Orthopaedic Surgery Research' [survey](#) conducted in partnership between the British Orthopaedic Association, NIHR and Versus Arthritis.

Applications will be assessed by our Treatment subcommittee. Awards of up to £750,000 and up to 60 months duration are available. We expect successful applications to be ambitious in aiming to make a step change towards defying arthritis and push for better answers for all affected. It is expected that every study will be delivered in conjunction with a UKCRC-registered CTU or affiliated personnel.

Applicants are invited to submit a clinical studies application to this two-stage process through Grant Tracker. The deadline for the receipt of outline applications is **16:00 on Wednesday 6 Feb 2019**.

About Versus Arthritis – demanding more for people with arthritis

Launched on the 19th September 2018, Versus Arthritis is a new charity formed from the merger of Arthritis Research UK and Arthritis Care. Building on the work and legacies of both charities, Versus Arthritis exists to push back the limits of arthritis. We are doing this by funding research, providing support and campaigning for the appropriate recognition for a condition that affects over 10 million people in the UK alone.

For far too long, arthritis has been viewed as something that is inevitable, insignificant and untreatable; shrugged off as 'just a bit of arthritis'. However, arthritis is none of these things and we no longer accept it as something that has to just be lived with.

VERSUS
ARTHRITIS

As Versus Arthritis, we will strive to do more and to be more ambitious in everything we do, working with and for people with arthritis. We will continue to campaign to challenge the misconceptions around arthritis to ensure that it is recognised as a priority in the UK. We understand what living with arthritis is like, and realise the strength it can so often require, and so whenever people are in need of help, we are here to support them. We are also bringing together researchers from across the world, funding them to develop more and better treatments to help the many number of people with arthritis who are living in pain without access to good enough care or treatment.

There's a lot to be done, but we won't stop until no-one has to tolerate the pain, fatigue and isolation of arthritis. We're 10 million people living with arthritis. Together, we're stronger. We are Versus Arthritis.

Background

In funding clinical research we seek to deliver healthcare science that develops and evaluates the safety, efficacy and effectiveness of medications, devices, diagnostic products and treatment regimens intended for human use. These may be used for prevention, treatment, diagnosis or for relieving symptoms of a disease.

Prioritisation activities highlight the known important unanswered research questions and can shine a light on previously unrecognised research questions. Setting research priorities can avoid the neglect of important areas of need, maximise patient benefit and channel research to important unanswered questions, bringing us to the answers faster.

Historically our clinical research priorities were determined by our seven Clinical Studies Groups (CSGs), which identified, and published, key priority areas and study questions designed to improve patient outcome in given disease areas. Our CSGs were largely stood down in 2016 (the Paediatric rheumatology CSG remains fully operational) and a part of their legacy is the priority areas they determined through strategy workshops. The CSGs considered factors including societal need, patient perspective, personal impact and healthcare demand and held widespread consultations via workshops and other forms of discussion to take into account the views of relevant stakeholders in reviewing and determining the consensus areas of focus.

Currently our Treatment subcommittee receives applications drawing on the pre-existing CSG priorities as well as further research prioritisation exercises developed by other organisations, some in combination with patients. These include the European League Against Rheumatism (EULAR)'s RheumaMap and NIHR's James Lind Priority Setting Partnerships.

Scope of the 2019 Priorities in Clinical Research Call

We aim to fund innovative research that addresses key clinical research priorities which will change practice and impact patients utilising novel trial design and methodological approaches on the basis of established feasibility and pilot work.

There is an expectation that applicants involve people with arthritis in the development of the outlined work as well as collaborating with them in the delivery of the proposed research.

Applicants must carefully read the application form and [guidance documentation](#) to ensure that the most appropriate language is being used in each section of the form.

Applications are invited to our Treatment subcommittee for clinical research funding focused in the priority areas defined in the strategies defined by:

- [Adult inflammatory arthritis](#)
- [Autoimmune rheumatic disorders](#)
- [Spondyloarthropathies](#)
- [Metabolic bone disease](#)
- [Osteoarthritis and crystal diseases](#)
- [Musculoskeletal pain disorders](#)
- [Paediatric rheumatology](#)
- [RheumaMap](#)

*NIHR's James Lind Priority Setting Partnerships:

- [Hip and Knee Replacement for osteoarthritis](#)
- [Early Hip and Knee Osteoarthritis](#)
- [Surgery for Common Shoulder Problems](#)
- [Common Conditions Affecting the Hand and Wrist](#)

* NIHR, Versus Arthritis and British Orthopaedic Association survey results

- [Identifying Research Priorities for Elective Orthopaedic Surgery Research](#)

**Applicants should be aware that some priorities referenced in the James Lind Alliance Priority Setting Partnerships and the results of the Elective Orthopaedic Surgery Research survey are beyond the scope of this call. Please see below further information regarding the disease areas within scope and areas of research not within the scope of this call.*

Applicants must state which priority question their clinical research proposal aims to answer.

Clinical research applications can be situated anywhere on the clinical research pathway from first in human (including experimental medicine) to larger phase III studies. Your proposed clinical study is expected to aim to make a step change towards defying arthritis and push for better answers for all affected.

Further to applications focusing on priority areas, the charity would like to see applications bringing together collaborative partnerships of existing groups, different disciplines and applications from researchers new to the field of musculoskeletal diseases. We welcome applications which seek to use novel methodological and experimental designs and/or make use of advances in technology and computing (such as artificial intelligence).

The **Treatment Subcommittee has two current Calls for applications, running on concurrent timelines.** Proposals with a primary hypothesis focused on approaches to developing and testing new treatments for managing musculoskeletal pain are beyond the scope of this this Treatment Subcommittee Call for applications in Priorities in Clinical Research and should be submitted to the Subcommittee via the [Pain Challenge](#). Studies employing pain outcome measures but aimed at

investigating broader musculoskeletal disease management and treatment fall within the scope of the Priorities in Clinical Research Call.

Areas beyond the scope of this call:

- Proposals aimed at health services research are ineligible and should be directed to [calls open](#) to the charity's Health Subcommittee (current call, Pain Challenge).
- Studies exploring the acute management of musculoskeletal trauma.
- Requests to complete systematic reviews.
- Proposals with a primary hypothesis focused on approaches to developing and testing new treatments for managing musculoskeletal pain; such studies could be more relevant to the concurrent call, [Pain Challenge](#).

Please contact the research team for guidance (research@versusarthritis.org) regarding the scope of the Calls and the relevance of your application.

Disease areas

We use the term 'arthritis' in its broadest possible sense, to include all associated musculoskeletal conditions affecting joints, bones and muscles (including back pain), along with autoimmune diseases such as lupus and other rarer forms of arthritis. Further information on conditions that are within scope can be found on our [website](#).

Cross-disease applications, as well as single disease focused studies, will be accepted. Applications specific to rarer forms of arthritis and across the life course (including arthritis in children, adolescents and older adults) are encouraged.

Types of study

Study designs which address a priority question may encompass:

- Interventional, hypothesis-led testing trials (encompassing prevention trials, screening trials, diagnostic trials, treatment trials, quality of life trials) of drugs, vaccines, surgeries, psychological, physical, radiotherapy and educational interventions.
- Observational, hypothesis-led, uncontrolled outcome measurement studies (encompassing prospective cohorts, retrospective cohorts, time series studies, case control studies, nested case control studies, cross sectional studies). These studies, which will typically be small scale, should have hypothesised outcomes which specifically lead to change in clinical management directly or will be used to inform the development of a clinical trial to test an intervention.
- Pilot and feasibility studies for clinical trial recruitment, biomarker validation and outcome assessments.
- Opportunities for research 'add-ons' to clinical trials and related studies are acceptable.

Feasibility Studies

Pieces of research done before a main study. Feasibility studies do not evaluate the outcome of interest, that is the function of the main study. Feasibility studies are used to estimate important parameters that are needed to design the main study, for instance, standard deviation of the outcome

measure as needed to estimate sample size; willingness of participants to be randomised; willingness of clinicians to recruit participants; number of eligible patients; characteristics of the proposed outcome measure; designing a suitable outcome measure; assessment of follow-up rates; response rates to questionnaires; adherence/compliance rates etc.

Feasibility studies for randomised controlled trials may not themselves be randomised. If a feasibility study is a small randomised controlled trial, it need not have a primary outcome and the usual sort of power calculation is not normally undertaken; the sample size should be adequate to estimate the critical parameters (e.g. recruitment rate) to the necessary degree of precision.

Pilot Studies

Applications for pilot studies will be supported, being defined as a version of the main study that is run in miniature to test whether the components of the main study can all work together. It is focused on the processes of the main study, for example to ensure recruitment, randomisation, treatment, and follow-up assessments all run smoothly. It will therefore resemble the main study in many respects. In some cases, this will be the first phase of the substantive study, an internal pilot, and data from the pilot phase may contribute to the final analysis or at the end of the pilot study the data may be discretely analysed.

Study development and delivery

Definitive assessment studies must be well-founded on pilot studies or distinct feasibility evidence relating to outcome measure selection, study design and statistical methods, subject recruitment and retention and delivery of the intervention. Applications defining feasibility studies to identify these parameters will be accepted.

Clinicians, patients/carers and methodologists should collectively identify the approach to be taken to gather all parameters needed to formulate the definitive study. Methodologists should be within a registered clinical trial unit (CTU) or the research design service (RDS) or MRC methodology hub.

Acknowledging the complexity of running a clinical study and the input required from a multidisciplinary team with relevant expertise, **it is expected that every study will be developed and delivered by an UKCRC-registered CTU or affiliated personnel <http://www.ukcrc-ctu.org.uk/>, or be engaged in a mentorship arrangement, unless circumstances are such that this is less appropriate.** If it is considered that the study does not require the support of a CTU, because there is adequate equivalent expertise within the team in lieu of CTU engagement, applicants should contact the office research@versusarthritis.org to discuss and confirm that there are appropriate proposed arrangements. This applies to non-clinical trials of investigative medicinal products (non-CTIMPs) as well as CTIMP studies. **CTUs should be contacted well in advance of submission of your outline application which must demonstrate an active collaborative CTU involvement in the study design.**

Investigators wishing to apply to the Treatment subcommittee for clinical research funding do not require Clinical Studies Group endorsement.

Application and assessment process

Application content

Applicants should review the [remit](#) of the Treatment subcommittee and ensure the application is within this remit prior to deciding to begin an application. Please contact the Research team for further advice if you are unsure whether the application meets the remit of the subcommittee (research@versusarthritis.org).

Investigators wishing to apply to the Treatment subcommittee for clinical research funding do not require Clinical Studies Group endorsement.

Applicants should indicate in the application form the alignment of the proposal a defined priority area.

Applicants should take care to ensure future patient benefit is clearly, and reasonably, discussed within the application.

Who can apply and what you can apply for

Applications should pose innovative and novel approaches to address the priority questions, providing a clear pathway to success.

Awards of up to £750,000 are available for up to 60 months. Costs for salaries, expenses and small items of essential equipment can be requested.

We encourage applications from both new and established researchers. At least one of the applicants must have a tenured position within a UK university, hospital or recognised academic research institute. We welcome applications from early career investigators and trialists however fellowship applications or applications to fund a fellowship as part of a clinical trial will not be accepted.

Collaborations with international and industrial partners are encouraged, additional guidance regarding industrial collaborations can be found on our [website](#).

Further information and general guidance for applicants can be found in the associated [guidance documentation](#).

Treatment Costs

The way in which Excess Treatment Costs (ETCs) are paid for within clinical research is changing and a trial period for the new arrangements is effective from 1 October 2018 through to April 2019. Versus Arthritis is engaged with the new system to manage the payment of ETCs. Further information can be found on the [NIHR website](#) and in their [route map](#).

Applicants are required to complete a new form, the 'Schedule of Events Cost Attribution Template (SoECAT)' for clinical research being undertaken in England. This form captures the different costs associated with clinical research and attributes them to different categories accordingly. Clinical research that is not considered to involve ETCs are still required to provide a completed SoECAT.

Applicants are not required to submit a SoECAT at the Outline application stage. However, if invited to submit a full application, applicants must complete and submit the SoECAT in partnership with the lead clinical research network (CRN). **It is strongly recommended that applicants engage with their lead CRN as early as possible to notify them** that they are submitting a clinical research outline application to this call and that CRN input will be required in the future if invited to submit a full application.

Application stages

There is a two-stage application process for all applications, regardless of funding level. At the first stage applicants are invited to submit an outline application which provides an overview of the project and funding requested. This should be submitted through [Grant Tracker](#) where the outline form is available. The deadline for the receipt of outline applications is 16:00 on **Wednesday 6 February 2019**. Submissions after 16:00 will not be accepted.

Applicants successful at the outline stage will be invited to submit a full application through [Grant Tracker](#) which will request more detailed information on the proposal. Where possible feedback will be provided, allowing an opportunity for applicants to adjust their submissions for the full application stage in line with subcommittee comments.

Only applicants approved through the outline stage will be eligible to apply for a full application. The deadline for the receipt of full applications is 16:00 on **Wednesday 19 June 2019**. Submissions after 16:00 will not be accepted.

Assessment

Assessment by people with arthritis forms a key part of the review process and is integrated into all assessment stages. Further information and guidance can be sought via our [website](#) or by emailing our Research Involvement team (Patientinsight@versusarthritis.org).

How will outline applications be assessed

Outline applications will be assessed by our Treatment subcommittee, supplemented with additional international and national experts where required.

Outline applications will be assessed on:

- Relevance to the scope of the call
- Importance, novelty and whether it meets an unmet clinical need
- Significance of the research outputs on the route to patient benefit and impact*
- Involvement of people with arthritis
- Quality and appropriateness of the research design and methodology
- Feasibility
- Value for money

**We do not necessarily expect immediate or near-term benefit for some types of research, but applicants should carefully consider how research outputs may be translated to future patient benefit.*

How will full applications be assessed

All full applications will undergo external expert peer review. Following peer review, applications may undergo a triage stage based on reviewer feedback prior to the final committee meeting. Those applicants who are successful at the triage stage will be given opportunity to respond to reviewer's comments before final assessment by the Subcommittee. The criteria used to assess full applications includes:

- Relevance to the call
- Potential for long term impact on quality of life for people with arthritis
- Involvement of people with arthritis in the proposed research
- Quality of the research design and methodology
- Strength and make-up of the research team, including multidisciplinary collaboration and proposed management arrangements
- Applicants' track record (or applicants' potential for smaller project awards) and ability to deliver the proposed research
- Applicants' ability to deliver, appropriate experience and facilities to conduct the proposed research
- Feasibility, the potential to deliver the stated outcomes within the timescales and budget
- Value for money
- The peer review comments and applicant rebuttal

Award management

It is expected that all research awards will report annually via Researchfish and 6 monthly to the Progress Review Committee. During the course of the award applicants may be invited to meetings with Versus Arthritis to discuss their research findings and/or asked to contribute written summaries.

Timelines

Call opens	Wednesday 28 November 2018
Deadline for outline applications	Wednesday 6 February 2019
Notification and Feedback	Mid-April 2019
Full application opens	Late April 2019
Full Application deadline	Wednesday 19 June 2019
Notification and Feedback	December 2019

Contact details

For enquiries, please contact research@versusarthritis.org