

Pain Challenge 2019

Summary

Understanding, treating and managing pain is among the greatest challenges facing healthcare today and is a high priority for people with arthritis. We believe that supporting innovative research will produce a fundamental change in how we understand and treat musculoskeletal pain. Since 2015, we have expanded our portfolio of musculoskeletal pain research by over £10 million and plan to continue this growth and investment through this new call.

In this Pain Challenge 2019 call we have carefully listened to the feedback from applicants and subcommittee reviewers as part of our pain challenge review. This feedback has been incorporated into the ambition, scope, structure and process of the call.

Research awards are available for discovery, clinical or applied health pain research, which will be assessed by our Disease, Treatment and Health subcommittees. Awards of up to £1 million, for up to 60 months, are available. We expect awards to be aligned with the priority areas set out later in this document, which are informed by the priority areas in our [research roadmap for pain](#). We expect that awards funded through this call to be collaborative, multidisciplinary, and address pain holistically. It is expected that all clinical studies will be delivered in conjunction with a UKCRC-registered CTU or affiliated personnel. There is an expectation that applicants will 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 are invited to submit applications to this two-stage process through Grant Tracker. The deadline for the receipt of outline applications is **16:00 on Wednesday 6 Feb 2019**.

As well as investing in innovative research awards, over the coming months we will announce plans to support early career pain investigators. Further details about this will be announced in 2019. However, we expect that for the early career investigator scheme, we will be able to offer ring-fenced funding for up to 18 months, to support the salary and research expenses of future leaders in pain research. These awards will support new researchers and academics at the start of their careers to become independent researchers. Applicants must not have received a significant research award (in excess of £100,000) as principal investigator. This does not include personal fellowships. Early career investigators may apply to this pain challenge call or wait for the ring-fenced early career investigator scheme, but concurrent applications to both schemes will not be accepted. We expect to launch the early career scheme in early 2019 with award decisions at the same time as this Pain Challenge 2019 call.

If you have any questions about this call document, eligibility or would like to discuss your research proposal with the office before starting an application please email research@versusarthritis.org

About Versus Arthritis – demanding more for people with arthritis

Launched on 19 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.

**VERSUS
ARTHRITIS**

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.

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 to the call

For people with arthritis, pain is life-changing. Up to 28 million people in the UK are affected by chronic pain, 75% of which is musculoskeletal in origin.

Although progress has been made, ongoing moderate and severe chronic pain remains a substantial daily problem for people with arthritis, even when the underlying disease is controlled (inflammatory arthritis) or removed completely (joint replacement in osteoarthritis). This pain often persists for decades, is poorly controlled by current treatment options and is comorbid with debilitating fatigue, cognitive and mental health issues.

Despite the prevalence of chronic musculoskeletal pain and impact on quality of life and the economy, research funders and the government have been slow to address the problem; compared with the investment made in other less prevalent or impactful conditions, pain receives a disproportionately low level of funding in the UK. Nevertheless, in terms of excellence, the UK continues to be a world leader in pain research. Over recent years significant advances have been made in our understanding of musculoskeletal pain and how healthcare professionals approach its management.

Versus Arthritis is committed to tackling the growing public health issue of chronic musculoskeletal pain and catalysing new levels of UK-wide investment in this area of critical need. Our [research roadmap for pain](#) outlines the most pressing and vital areas for future pain research, and highlights the key priorities for research funders to address. Through this call we seek to support ambitious research which addresses these challenges.

Scope of the Pain Challenge 2019

Through this call for applications we are striving to fund proposals which seek to address the priorities listed below and in our research roadmap for pain. Applicants should involve people with arthritis in the development of their proposal, as well as collaborating with them in the delivery of the proposed research.

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.

Please note, **priority areas in bold** are broad research themes, built on the priorities identified in our research roadmap for pain. We have included important research questions under each heading, but proposals are not limited to only these questions. Applicants should state which priority question their research proposal will aim to answer within the application form.

Advancing our understanding of the complexity of musculoskeletal pain, including:

- Identifying underlying pain mechanisms which support the development of new treatments.
- Research into co- and multi-morbidities associated with musculoskeletal pain and the impact of poly-pharmacology.
- Research in under-represented and hard-to-reach groups, including engaging such groups.
- Exploring how early life experiences influence later life pain.
- Mechanisms that sustain chronic idiopathic pain.

Preventing musculoskeletal pain, including:

- Preventing the transition from acute to chronic pain.
- Identifying 'red flags' or risk factors for developing chronic pain and how/when to intervene.
- Exploring the organisation of healthcare services to support prevention.

Developing more effective and patient centric approaches to the identification, assessment, measurement, or evaluation of musculoskeletal pain, including:

- Identification of musculoskeletal pain phenotypes and prototypical behavioural responses, their drivers, scientific/clinical utility and trajectories.
- Better assessment in both animal models and humans.
- Development of objective and quantifiable measures of musculoskeletal pain and key behaviours relevant to pain such quality of life, fatigue, disability and mental health.
- Developing and testing workplace interventions.
- Establishing agreement on clinical endpoints in trials of treatments for musculoskeletal pain.

Developing or testing new approaches to treating and managing musculoskeletal pain, including:

- Investigating how best to initiate, maintain and support adaptive behavioural change in supported self-management of chronic pain.

Exploring the impact and outcomes of musculoskeletal pain in the workplace, including:

- Establishing broad economic impacts of pain and effects on presenteeism.
- Utilising existing data from life-course epidemiology studies to understand workplace impacts and outcomes.

Additional considerations within the scope of this call:

- As with all our challenge calls, we expect all applications to involve and consider the needs of people with arthritis in their design.
- Applications should be collaborative and multidisciplinary, particularly for large scale funding applications.
- Collaborations with international partners are welcome.
- Collaborations with industry partners are encouraged. Further information can be found on our [website](#).
- In line with our research roadmap for pain, we welcome applications aiming to use novel methodological and experimental designs and/or making use of advances in technology and computing (such as artificial intelligence).
- Clinical research applications can be situated anywhere on the clinical research pathway from first-in-human to larger phase III studies.
- We are delighted to be partnering with the MRC and NIHR methodology research programme on a themed opportunity on research proposals for [data and measures in pain research](#). We encourage any applicants considering applying to this pain challenge with a proposal that would fall under the MRC/NIHR opportunity to contact us before submitting an application.
- NIHR have recently launched a [themed call in chronic pain](#) across all of their programme boards. Whilst we continue to explore engagement and partnership with the NIHR through this themed call we encourage applicants with proposals that span both the remit of Versus Arthritis subcommittees and NIHR programmes to contact us to discuss their application as early as possible.
- Applicants with proposals that have agreement for part-funding from a third party are not excluded, but applicants should contact us to discuss their application as early as possible.

Areas beyond the scope of this call:

- Studies exploring the acute management of musculoskeletal trauma.
- Requests to complete systematic reviews.
- Studies with a primary focus or hypothesis of managing or treating musculoskeletal disease, where pain is only used as the outcome measure to assess this; such studies could be more relevant to the concurrent call, [Priorities in clinical research](#).

If required, please contact the research team for guidance (research@versusarthritis.org) on the scope of the call 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). This also includes autoimmune

conditions, 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.

While applications are expected to focus on aspects of musculoskeletal pain, it is recognised that the underlying mechanisms of pain may also be relevant to both musculoskeletal and non-musculoskeletal conditions. For applications with a non-musculoskeletal pain aspect, a strong justification and case for support should be made to illustrate its relevance to, and potential impact for, musculoskeletal pain.

Clinical and applied research studies

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, 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

Applications are invited to our Disease, Treatment and Health subcommittees. Applicants should review the [remit](#) of our three subcommittees, prior to deciding which subcommittee to submit their application to. Applications which come under the remit of more than one subcommittee should be submitted to the subcommittee that best fits the predominant focus of the research. Please contact the research team for further guidance (research@versusarthritis.org) if you are unsure which subcommittee to submit to.

Applicants should indicate the alignment of the proposal to a defined priority area, listed above, in the application form.

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

Awards of up to £1 million, for up to 60 months, are available. Costs for salaries, expenses, animals (where relevant) and small items of essential equipment can be requested. For further details on what you can apply for, please see the associated [guidance document](#).

At least one of the applicants must have a tenured position within a UK university, hospital or recognised academic research institute.

Applications for small to medium awards and trials should seek to answer a single question, or a small group of related objectives. This may also include requests for short small-scale exploratory projects, which seek to bring together researchers from multidisciplinary groups, in order to develop and refine research plans, and generate preliminary data for future programmes of work.

More substantial funding of up to £1 million is available for trials and significant bodies of research, which seek to answer an interrelated set of questions on a broader front than would be feasible in a series of smaller awards. Applications should pose innovative and novel approaches to meet the challenge of the initiative, providing a clear pathway to success and patient impact. Applications for larger/long-term awards should be led by established groups, able to demonstrate highly competitive research track records. Applications can include lead applicants and/or co-applicants with expertise relevant to this initiative, but who do not have a track record of musculoskeletal research. We expect applications to take a collaborative and multidisciplinary approach to answering research questions. Patient partners may be included as co-applicants.

Further information and general guidance for applicants can be found on the Pain Challenge 2019 [webpage](#). Please read the associated [guidance documentation](#). For any pre-clinical studies using animal models, applicants should additionally read our [policy on animal research](#).

Treatment Costs

The way in which Excess Treatment Costs (ETCs) are paid for clinical research is changing and a trial period for the new arrangements will roll out from 1 October 2018, through to April 2019. As a funder we are 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](#).

Researchers are required to complete a new form known as a 'Schedule of Events Cost Attribution Template (SoECAT)' for clinical research being undertaken in England. This form is designed to capture the different costs associated with clinical research and attribute them accordingly. Clinical research that is not thought to involve ETCs will still need to provide a completed SoECAT.

Applicants are not required to submit a SoECAT at outline stages. However, if invited to submit a full application, applicants must complete and submit the SoECAT in partnership with their 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 that provides an overview of the project and funding requested. This should be submitted through [Grant Tracker](#), where the outline form is available. Applicants should select the appropriate outline form for the subcommittee they wish to submit to. 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 panel 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 found on 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 subcommittees, 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 and the potential to deliver the stated outcomes within the timescales and budget
- 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 this triage stage will be given a chance to respond to reviewer's comments before final assessment by the Subcommittees. 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 and 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, clinical projects will report every six months 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 all enquiries, please contact research@versusarthritis.org