Call for Applications

Summary

Clinical research delivers 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.

Review and recommendation of clinical research funding is being undertaken by our Treatment subcommittee, which has now replaced our previous Clinical Studies Subcommittee. Since 2008, clinical research priorities have been determined primarily by our seven Clinical Studies Groups which were established to develop strategies that identified the key priority areas and study questions designed to improve patient outcome in given disease areas. Apart from the Paediatric group, the Clinical Study Groups are no longer operating and are in the process of being replaced with new Research Advisory Groups. Future priority areas will be determined by the charity and the Disease, Treatment and Health subcommittees with input from the Research Advisory Groups which will build on the activity of the previous Clinical Studies Groups.

The present call for the Treatment subcommittee is seeking to continue to draw on the Clinical Studies Group activities, calling for **applications for clinical research funding in the areas defined in the strategies put forward by the Clinical Studies Groups**. We aim to fund innovative research that seeks to address key clinical research priorities that will change practice and impact patients, utilising novel trial design and methodological approaches on the basis of established feasibility and pilot work. It is expected that every study will be delivered in conjunction with a UKCRC-registered CTU or affiliated personnel, unless circumstances are such that this is less appropriate.

Applicants are invited to submit an initial outline application to this two-stage process through Grant Tracker. The deadline for the receipt of outline applications is **16:00 on Thursday 31st August 2017**. If successful at the outline stage applicants will then be invited to submit their research proposal as a full application through Grant Tracker.

Background

The charities' purpose, as redefined in 2015, is to prevent the onset of arthritis, develop a cure for arthritis and transform the lives of those with arthritis, and our five-year strategic focus to 2020 is to make a positive and tangible change in the quality of life for people with arthritis so they can say "I am in control, independent and recognised". In aligning our funding towards our purpose and strategic focus to 2020, we have issued research highlights and funding calls in the areas of pain and fatigue and health services research.

In 2016 we implemented a new approach to future research funding by establishing a new strategic oversight committee, the Charitable Purposes Committee, and three new sub-committees titled Disease, Treatment and Health in different domains of research activity.

The Treatment subcommittee has now replaced the Clinical Studies Subcommittee for review and recommendation of clinical research funding. Clinical research delivers 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.

Since 2008, clinical research priorities have been determined primarily by our seven Clinical Studies Groups, which were established to develop strategies that identified the key priority areas and study questions designed to improve patient outcome in given disease areas. The Clinical Studies Groups 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 all relevant stakeholders in reviewing and determining the consensus areas of focus. Investigators wishing to apply to the Clinical Studies Subcommittee for clinical research funding were required to seek endorsement by the Clinical Studies Group confirming the proposal sought to address a question considered by stakeholders to be of key importance. The Clinical Studies Subcommittee operated with due acknowledgement of the process by which the areas of focus had been established and for the most part the questions that investigators sought to address in their applications for funding were endorsed.

Going forward priority areas will be determined by the charity and new Disease, Treatment and Health subcommittees. Priority areas will be defined with input from the clinical/scientific research and patient communities, thus the Clinical Studies Group processes for prioritisation of key areas are to be transitioned and integrated with the charity prioritisation processes in new ways of working. Investigators wishing to apply to the Treatment subcommittee for clinical research funding do not now need to seek endorsement by a Clinical Studies Group as a mandatory step.

The present call for the Treatment subcommittee is building on success of the previous Priorities in clinical research call and will to continue to draw on the Clinical Studies Group priorities defined strategies. Applicants will no longer be able to seek/utilise Clinical Studies Group for review of the proposed study question, but can confirm with the charity that their study question is in line with the priorities of the outgoing Clinical Study Groups.

In this funding call the charity seeks **applications for clinical research funding in the priority areas defined in the strategies put forward by the Clinical Studies Groups**. We aim to fund innovative research that seeks to address key clinical research priorities that will change practice and impact patients utilising novel trial design and methodological approaches on the basis of established feasibility and pilot work.

Focus areas

The Clinical Studies Group strategies are laid out in seven domains, each group has a **current website page and the individual group's strategy can be referenced there:**

- Adult inflammatory arthritis
- Autoimmune rheumatic disorders

- Spondyloarthropathies
- Metabolic bone disease
- Osteoarthritis and crystal diseases
- Musculoskeletal pain disorders
- Paediatric rtheumatology

There are some common areas prioritised across some Clinical Studies Groups strategies, for example outcome measure development, predictors of response, treatment optimisation in relation to stratification / tolerability / incomplete response / reducing treatment load, multi-morbidities, pain and physical activity.

There are workshop reports to further inform the nature of the key questions in a given area:

Adult inflammatory arthritis group	Non-pharmacological interventions (2015)
Osteoarthritis group	Obesity (2014)
Spondyloarthropathies group	Stratified medicine (2014)
Adult inflammatory arthritis group	Moderate disease (2014)
Adult inflammatory arthritis group	Comorbidity (2013)
Osteoarthritis group	Packages of care (2012)

Note on musculoskeletal trauma: we do not support studies exploring the acute management of trauma.

Patient and public involvement

Lay assessment by people with arthritis forms a key part of the review process and is integrated into our assessment stages. As such, applicants should not only carefully consider the lay information in the application form but also the use of language throughout the application form. There is an expectation that applicants demonstrate how they have involved people with arthritis in the development of the approach as well as how they plan to collaborate with them in the proposed research. Guidance for this can be sought from our Research Involvement team at the charity (Patientinsight@arthritisresearchuk.org).

Types of study

Study designs which may address these priority questions, 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 development 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 left to 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 and methodologists should collectively identify the approach to be taken to gather all parameters needed to formulate the definitive study. Methodologist 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 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** and shown to have had an active collaborative involvement in the study design.

Application and assessment process

Who can apply

Applications are encouraged from both new and established researcher groups. At least one of the applicants must have a tenured position within a UK university, hospital or recognised academic research institute.

The lead applicant and co-applicants may apply for their own salary as long as they don't already hold a tenured position and at least one of the co-applicants has a tenured or permanent position.

Fellowships aren't funded within clinical studies; justification in support of such a post may be provided for consideration.

What you can apply for

- **Value**

There is no financial limit to a clinical studies grant application. Costs must be attributed as Research, Support or Treatment according to the English Department of Health AcoRD guidelines. Costs for salaries, expenses, and small items of essential equipment can be requested.

Collaborations with international and industrial partners are encouraged for all applications and additional information about industrial collaborations can be found on our website.

- **Duration**

There is no limit to the duration of the proposed study.

How to apply

There is a **two-stage** application process for all applications. 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 forms are available. The deadline for the receipt of **outline applications** is **16:00 on 31 August 2017**. 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 reshape 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 4 January 2018**. Submissions after 16:00 will not be accepted.

Further information on what you can apply for can be found in the guidance document.

How outline applications will be assessed?

Outline applications will be assessed by the Treatment subcommittee. The criteria used to assess outline applications include:

- Relevance to the scope of the 2017/18 Priorities in Clinical Research call

- Importance, meets an unmet clinical need
- Impact: significance of the research outputs on the route to patent benefit and clinical need
- Involvement of people with arthritis
- Quality and appropriateness of the research design and methodology
- Feasibility and ability to deliver
- Value for money

How will full applications be assessed?

The criteria used to assess full applications include:

- Relevance to the scope of the 2017/18 Priorities in Clinical Research call
- Clinical impact
- Potential for impact on the quality of life for people with arthritis
- Involvement of people with arthritis in the proposed research
- Scientific merit, quality of the research design and methodology
- Feasibility of the approach and potential to deliver the stated outcomes
- Value for money
- Applicants' track record and ability to deliver the proposed research, strength and make-up of the research team, including multidisciplinary collaboration and proposed management arrangements

Full applications will be subject to external peer review. Applicants will be given the opportunity to give a rebuttal to the peer reviews and Arthritis Research UK research directorate review using a maximum of four pages. This is provided in advance of the Treatment subcommittee meeting and will be considered at the review meeting.

Monitoring of awards

All research awards made will report every 6 months to the Progress Review Committee and annually via Researchfish. During the course of the award applicants may be invited to meetings with Arthritis Research UK to discuss their research findings and/or asked to contribute to written summaries.

Timelines

Call opened:	12 June 2017
Deadline for outline applications:	31 August 2017
Notification and feedback:	October/November 2017
Full application deadline:	4 January 2018
Funding decision:	May 2018
Notification and feedback:	June/July 2018

Contact details

For enquiries, please contact **research@arthritisresearchuk.org**