

Arthritis Research UK – Research Policy

- observational data and sample collection

This policy presents the principles that guide Arthritis Research UK's support of clinical observational data and sample collection.

These principles encompass collection and maintenance of *data and samples* for both proposed *new* collections and *established* collections and are intended to serve as a guide for those wishing to apply for support or such studies to Arthritis Research UK.

It is important that all potential applicants for support consider carefully the scope of their application and its relevance to Arthritis Research UK's mission and strategic focus.

As well as the criteria set out below, the charity will consider carefully the overall cost of each study, whether it has support from other funders and the plan for longer term sustainability.

Preliminary enquiries regarding the scope and suitability of a study for potential support by Arthritis Research UK can be made via the Clinical Studies Groups and the Research and Programmes Directorate.

Principles of support

i. Purpose of collection; descriptive vs analytical

Arthritis Research UK will consider support for observational data studies seeking to *answer a defined research question*, focussing on particular unmet patient need by employing an analytical observational hypothesis-testing study design (cross-sectional, case-control, cohort study).

Descriptions of prevalence, incidence of disease, outcomes from disease or outcomes from treatment can inform clinical practice and service provision or provide treatment safety information.

Arthritis Research UK will only consider non-comparison, *non-hypothesis testing* studies if it is evident that major value will be forthcoming, in the sense that the results will provide a strong future influence in the intended area. Cohorts in themselves, as open-ended "gather and see" collections are not supported.

ii. The collection population; disease-based vs non-disease-based

Primarily Arthritis Research UK considers support for clinical observation studies that are characterised by musculoskeletal disease or treatment, that seek predictors of outcome and identification of risk.

Arthritis Research UK will consider support for modest prospective population cohort studies to identify risk of disease, particularly in relation to occupational studies and common diseases.

Arthritis Research UK will not normally or exclusively consider support for broad, prospective, large-scale, (cross-sectional or cohort) studies in non-disease populations that present descriptive outputs of prevalence or incidence, unless the proposed output is pivotal to Arthritis Research UK strategic priorities.

iii. Utilisation of existing collections and linkage

Arthritis Research UK expects the approach to prospective cohort studies (longitudinal collection) to exploit the opportunities available for linkage with routine and other data collection.

Arthritis Research UK will consider support for exploitation of population data sources via analysis of follow-up data within existing collections such as ALSPAC, UK Biobank or of routine data collections. Similarly, Arthritis Research UK will consider support for additional collection in relation to existing population, for example x-rays, if there is an hypothesis-driven approach to the further collection.

iv. Partnership

Arthritis Research UK seeks that, wherever possible, support for larger scale prospective cohort studies should be provided in partnership with others.

Arthritis Research UK will consider providing financial support as the single funder for smaller studies in rare diseases or sub-population of diseases.

v. Duration

Arthritis Research UK will generally consider support for new prospective cohort studies for a maximum of 5 years collection without commitment to any longer term maintenance beyond the set-up and mid-term follow-up.

Arthritis Research UK does not seek to operate as the long term 'parent' of substantially long term cohort studies.

It is expected that beyond 5 years a self-sustaining model for such collections will be deployed. Arthritis Research UK may consider a commitment beyond 5 years if part of a shared commitment with others is clearly laid out in an appropriate sustainability plan.

vi. Established collections

Arthritis Research UK recognises the value of established collections, where emergent outputs from the long term data can provide valuable perspective in chronic diseases.

Arthritis Research UK will consider onward support to extend established prospective cohort studies (that have either been supported with previous Arthritis Research UK funding or supported via other funders) dependent upon the ongoing Arthritis Research UK funding capacity.

Interim support up to a maximum of four years duration may be considered to support transition in establishing a future sustainable model.

Arthritis Research UK may consider a commitment beyond 5 years if part of a shared commitment with others is clearly laid out in an appropriate sustainability plan. Amongst the considerations of such support account will be made of the quality of the data, the attrition rate with longer term collection, the relative currency of the associated question and evidence that the required end points are forthcoming as well as the change in scope for the long-term outcomes of interest to be gathered from linked data records.

vii. Retrospective collection

Arthritis Research UK will consider support for case-control studies or retrospective cohort analysis where it is evident that good quality data exists to deliver the analysis.

viii. Opportunistic sample collection

In line with the UKCRC's Funders Vision for Human Tissue Resources, Arthritis Research UK will consider provision of support for opportunistic sample collection in conjunction with definitive clinical studies or trials on a non-hypothesis basis. Such collection may be associated with studies that are about to commence or are ongoing, whether funded by Arthritis Research UK or another funder.

Arthritis Research UK supports opportunistic sample collection in conjunction with definitive clinical studies or trials where there is specific disease-based need. Support will be provided for the collection of bloods, specific justification can be made for the collection of additional samples.

Arthritis Research UK does not seek to operate as the long term 'parent' of such sample collections. Arthritis Research UK aims to support the primary collection allied to the clinical trial without commitment to any longer term maintenance. It is expected that beyond the primary collection a self-sustaining model for maintenance will be adopted.

ix. Principles of sample collection and maintenance

Reflecting Arthritis Research UK's commitment to the UKCRC Funders Vision for Human Tissue Resources, the charity expects that:

- Generic consent, broad in time and scope, to be sought to facilitate widest use
- Where standards and good practice for data and sample collection and maintenance are defined they must be adopted and applied
- Clear and robust data and sample access management procedures must be documented and implemented to allow wide access beyond the collection team
- Collections must be discoverable e.g. on a register such as the Musculoskeletal Catalogue of studies

New sample collections supported by Arthritis Research UK must meet these principles in their operation. Established cohort studies supported by Arthritis Research UK must seek to adopt these principles in their operation if not already in place.

Application

Taking account of these principles guiding the approach to support of clinical observational collections, initial enquiries should be made via a Clinical Studies Group or the Research office outlining whether the focus of the question is examination of the causes, progression and prognosis of disease or seeking to explore evaluation of treatment, prevention interventions, screening or diagnosis tools.