

Arthritis Research Program

Strategic Plan

INTRODUCTION

The Congressionally Directed Medical Research Programs, CDMRP, represents a unique partnership among the U.S. Congress, the military, and the public to fund innovative and impactful medical research in targeted program areas. Programs managed by the CDMRP formalize strategic plans that identify program-specific research priorities, how to best address these urgencies, short- and long-term goals, investment strategies, and ways to identify and evaluate program successes with respect to the priorities.

The Arthritis Research Program, ATRP, Strategic Plan identifies the high-impact research goals most important to the program and its stakeholders while providing a framework that is adaptable to changes in the medical research and clinical care environments to address those goals. The strategic plan is formulated to provide greater clarity of the program's goals over time. Congress appropriates funding for the ATRP on an annual basis; therefore, there is no guarantee of future funding. The ATRP Strategic Plan is reviewed during the program's annual vision setting meeting and updated as necessary.



ATRP BACKGROUND AND OVERVIEW

There are more than 100 types of arthritis and related diseases that can cause inflammation, swelling and/or pain around one or many joints leading to disability. Arthritis-related health care costs and loss of earnings due to disability from arthritis resulted in an estimated cost of \$303.5 billion in 2013.¹ According to the Centers for Disease Control and Prevention, arthritis is the leading cause of disability in the United States and affects over one-third of Veterans. Congress has a long history of supporting arthritis research with sizable investments at the National Institutes of Health, the U.S. Department of Veterans Affairs, and the CDMRP.

The CDMRP historically funded arthritis research under six programs – the Peer Reviewed Medical Research Program, the Peer Reviewed Orthopaedic Program, the Chronic Pain Management Research Program, the Joint Warfighter Medical Research Program, the Lupus Research Program and the Tick-Borne Disease Research Program, but no single CDMRP program received appropriations to specifically and solely support arthritis research until recently.

Through the Further Consolidated Appropriations Act, 2024, Congress appropriated \$10M in funding for peer reviewed arthritis research, which CDMRP is managing through the ATRP. The fiscal year 2024 ATRP challenges the scientific community to address gaps in care and well-being of Service Members and all persons impacted by arthritis.

The **VISION** of the ATRP is to lessen the burden of, and ultimately cure, arthritis.

The **MISSION** of the ATRP is to fund high-impact research to optimize the health and well-being of all people affected by arthritis and improve Service Member readiness and retention.

¹ Murphy, L. 2018. Medical Expenditures and Earnings Losses Among US Adults with Arthritis in 2013. *Arthritis Care Res* 70(6):869-876.



RESEARCH AND FUNDING LANDSCAPE

According to a National Health Interview Survey conducted during 2019-2021, more than 53 million people are living with arthritis in the United States. The statistic does not represent cases of juvenile arthritis or individuals without a formal diagnosis from their doctor. An additional 220,000 children under the age of 18 received an arthritis diagnosis as reported by their parents in a National Survey of Children's Health between 2017-2021. As mandated by Congress, the ATRP will support high-impact research on all types of arthritis, including but not limited to osteoarthritis, post-traumatic arthritis, inflammatory arthritis, juvenile arthritis, and rheumatoid arthritis.

The NIH, CDMRP and VA represent three of the largest federal funding sources for arthritis research, with the NIH contributing the most significant investment. Rheumatoid arthritis-focused research represents the largest investment when compared to research focused on osteoarthritis, post-traumatic arthritis, juvenile arthritis or inflammatory/autoimmune types of arthritis, as well as non-defined or non-specific types of arthritis, combinations of multiple arthritis, and less common types of arthritis. Across the three federal agencies, juvenile arthritis-focused research is only funded by the NIH. The CDMRP's current portfolio of arthritis-focused research is primarily invested in osteoarthritis and post-traumatic arthritis. In addition to federal support of arthritis research, several non-government organizations provide support to advance arthritis research, including but not limited to the Arthritis Foundation, the Arthritis National Research Foundation, the Childhood Arthritis and Rheumatology Research Alliance, the Research Rheumatology Foundation and the Orthopaedic Research and Education Foundation.

Program Considerations

In response to the FY24 ATRP congressional appropriation, the program released a public Request for Information, RFI, in April 2024 to help establish the current state of the science and identify knowledge gaps, targeted outcomes and product needs for those impacted by arthritis. The ATRP received and tabulated responses from nearly 350 stakeholders, including researchers, clinicians, program administrators and patients who completed the RFI survey. Respondents consistently noted diagnosis and treatment as having the most potential for high impact across all types of arthritis. For both rheumatoid arthritis and juvenile arthritis, respondents indicated that more research at the foundational science level also has the potential for high impact. Respondents indicated that research focused on prevention and monitoring would have a higher impact on osteoarthritis and post-traumatic arthritis areas but noted that foundational science research is also important. Collectively, across all research types and all types of arthritis, program stakeholders reported clinical and translational research as the main priority for arthritis, as shown in Figure 1.

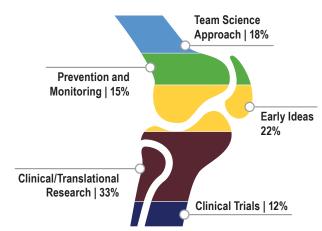


Figure 1: Analysis of the Type of Studies That Should Be Considered for Additional Investments Across All Arthritis Types, as Determined by RFI Respondents.

In May 2024, the ATRP held a virtual stakeholders meeting to engage arthritis research scientists, clinicians and military experts, as well as lived-experience subject matter experts/consumers, in an open-dialogue forum to:



Identify knowledge and capability gaps to help inform future investment discussions;



Identify the most impactful areas within the research continuum for additional arthritis research; and



Acknowledge barriers to implementation of interventions to reduce the burden of arthritis, particularly those related to the detrimental impact of arthritis on Service Members and their retention.

Stakeholder meeting attendees participated in breakout sessions organized by arthritis type and according to their areas of interest or expertise. Armed with the data from the RFI and other key information, each breakout group identified and prioritized key research gaps and suggested where to focus research efforts along the research continuum. In addition to reviewing the type of arthritis research conducted by each federally funded organization, stakeholders also examined the priorities of each organization as a whole and considered where gaps along the research continuum may exist in terms of foundational science, translational science, training and development research and team science. The stakeholders also provided general comments for the program to consider in the development of the ATRP priorities. Research gaps identified by the stakeholders can be found on the <u>ATRP webpage</u>.





The ATRP is mindful of its platform to target research that specifically impacts the unique challenges encountered by Service Members through its partnership with the military and also understands that benefit to the military can be applied broadly to include Family members of Service Members, Veterans, caregivers, and the general American public, any of whom can be affected by arthritis. For this reason, the mission of the ATRP outlines the goal to improve Service Member readiness and retention and optimize the health and well-being of **all** people affected by arthritis. Accomplishing this mission requires the ATRP to prioritize balancing funding across different types of award mechanisms, focus areas or program priorities and different arthritis types. The ATRP considers the degree of impact, the relevance to military health and a balanced program portfolio for every project recommended for funding.

STRATEGIC DIRECTION AND INVESTMENT STRATEGY

The field of arthritis research is vast. With over 100 arthritis types, the body of research is growing rapidly. Since the 1940s, scientists have made key discoveries leading to improvements in the diagnosis and treatment of arthritis, such as the discovery of cortisone in the 1940s, the recognition of crystals in joint spaces for the correct diagnosis of gout in the 1960s and the discovery of Lyme Disease in the 1970s,² to name a few. At times, patients and consumers become privy to advances in science before changes are implemented in clinical care. The ATRP routinely monitors the research landscape and will continue to engage a broad range of representatives, consumers and experts from multiple federal and nonfederal organizations to ensure that research is not duplicative or short-sighted.

During the inaugural FY24 ATRP vision setting meeting, the program reviewed the RFI data, top gaps identified during the stakeholders meeting, and current priorities of other federal funders. The following themes emerged in no particular order from the discussion as areas of particular interest to the program:

- Leveraging large data sources using computational and systems approaches or artificial intelligence to better understand the complex nature of arthritis diagnosis, treatment response and epidemiology
- Developing **new treatment modalities with targets at the local and systemic level** informed by a better understanding of the mechanisms underlying the disease
- Supporting animal, human-relevant, and computational model development that is specific to underrepresented groups and the development of models in large animals that can accelerate translation of promising therapeutics toward clinical trials
- Emphasizing **personalized medicine** as an area of focus for arthritis research
- Identifying biomarkers capable of **predicting the development or progression of disease**, especially in specific types of understudied populations
- Understanding disease heterogeneity and its role in therapeutic response and long-term outcomes

² Research on Arthritis. Patient Resources. (n.d.). https://orthop.washington.edu/patient-care/articles/arthritis/research-on-arthritis.html

Arthritis Research Program



The long-term goals of the ATRP are to lessen the burden of arthritis by developing effective methods and solutions for early detection, preventing progression and intervening to mitigate the severity of arthritis and/or cure the disease. The program intends to specifically address the following:

PREVENTION:

Identify materiel or knowledge products for the preventative management of arthritis.

DIAGNOSIS:

Address gaps in knowledge related to fundamental or clinical mechanisms to define arthritis and reduce delays to the diagnosis of arthritis; identify holistic phenotypes or biomarkers to identify those at greatest risk of disease onset or progression of arthritis.

PROGRESSION MITIGATION:

Identify effective strategies to reduce risk factors that prevent progression of arthritis; examination of arthritis as a cause of health disparities and its subsequent social impact, and the converse.

INTERVENTION/ TREATMENT:

Develop and/or validate therapeutic targets/approaches/ solutions/modalities that address the multifactorial burden of arthritis disease.

In addition to the program goals, the ATRP encourages research that addresses **sex as a biological variable** and **research in understudied arthritis types**. Researchers are also encouraged to consider whether large data sets or existing studies or consortia can be leveraged to maximize potential impact.

The ATRP will consider award mechanisms that are intended to be broad to capture a variety of gaps in the preclinical and clinical setting to capitalize on the greatest potential for short- and long-term impact. For the inaugural year of the program, the program released two award mechanisms in FY24: the Clinical Research Award, which supports both clinical research and clinical trials, and the Focused Research Award, which includes two research levels to support preclinical research at different stages of maturity. Both award mechanisms emphasize potential impact of the proposed study as a criterion for funding. The CDMRP will post all funded projects and their lay and technical abstracts on the organization's webpage for public access.

In subsequent fiscal years, if appropriated, the ATRP will review any language provided by Congress, the research landscape, researcher capabilities, patient needs and program portfolios annually during vision setting meeting discussions. These discussions may require a refinement of the program's strategic goals, award mechanisms and focus areas. The program will maintain interests in emphasizing translational and clinical research, supporting new and early career investigators in the field and encouraging team science. It is anticipated that the program's focus areas will be sharpened and narrowed within the next two to five years to best address the needs of the research and patient communities. ATRP will review and revise this strategic plan at least every 5 years or as needed, to capture any significant changes in program direction or goals.



MEASURING PROGRESS

The program will monitor the outcomes of ATRP-funded research projects using several key metrics organized by potential short-term and long-term impacts.



Short-term outcomes should be realized within three to five years and include evaluation of the amount of funding invested in each priority area and across arthritis types, number of publication citations, and the number of clinical trials funded. The program will also review its unfunded research applications to determine whether partnerships with external funding partners may be advantageous to optimize the program's limited funding.



Medium- and long-term outcomes will be realized after six or more years and may include metrics related to the proportion of funded investigators that receive follow-on funding to advance their research toward clinical implementation and the acquisition of and retention of new or early-career investigators in the arthritis field. The goal of these outcomes is to grow the arthritis research community to develop capabilities and novel ideas in research that will directly impact the lives of those living with arthritis in alignment with the program's long-term goals.



Outcome Metrics may also include the ATRP's involvement in improvements in patient-reported outcomes and quality of life, reduction in the reported financial burden of arthritis, reduction in the number of Service Members medically discharged due to arthritis-related disability and/or the development or update of Clinical Practice Guidelines for improvements in diagnostic care, preventative care or the treatment of arthritis.