



National Institutes of Health

REQUEST FOR INFORMATION SUMMARY

*NOT-OD-24-049: Inviting Input on an
NIH-Wide Strategic Plan
for Autoimmune Disease Research*

JULY 2025

Background

In December 2023, the Office of Autoimmune Disease Research in the Office of Research on Women’s Health (OADR-ORWH), in collaboration with a National Institutes of Health (NIH)-wide Strategic Plan Working Group (SPWG), published a Request for Information (RFI) ([NOT-OD-24-049](#)) that sought public input on advancing autoimmune disease research at NIH. RFI responses served as a critical source of data collated by the SPWG to set strategic priorities, objectives, and crosscutting themes for the inaugural *NIH-Wide Strategic Plan for Autoimmune Disease Research*.

The RFI closed in March 2024 with 83 responses from 80 unique respondents. Respondents were permitted to submit additional documentation that was not subject to a word limit; 1 video and 31 supplemental documents were received. Twenty-six respondents submitted on behalf of an organization, and 51 submitted on their own behalf. Respondents came from a variety of backgrounds, including academic, advocacy, industry, research, and scientific societies as well as people living with autoimmune diseases.

RFI Objectives

The RFI sought input on four objectives (Figure 1). Respondents could address one or multiple objectives. Objective 1 received the most responses, and Objective 4 received the fewest. Responses were reviewed and coded by OADR-ORWH staff. Staff identified overarching themes as well as common themes addressed by respondents.

SUMMARY OF RFI RESPONSES

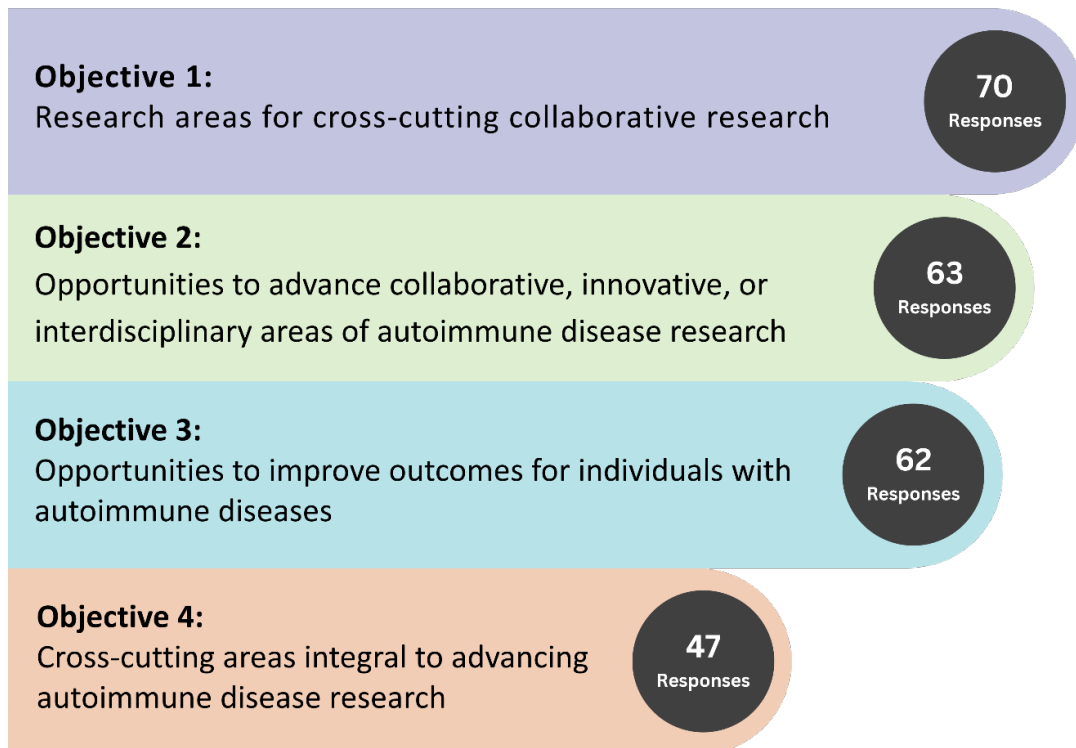


Figure 1. Four primary objectives identified through qualitative analysis of responses to the RFI: Inviting Input on an NIH-Wide Strategic Plan for Autoimmune Disease Research ([NOT-OD-24-049](#)).

Themes

RFI responses were collated and analyzed. Through this analysis, three overarching themes emerged focused on Scientific Advances, Research Methodology, and Workforce (Figure 2).

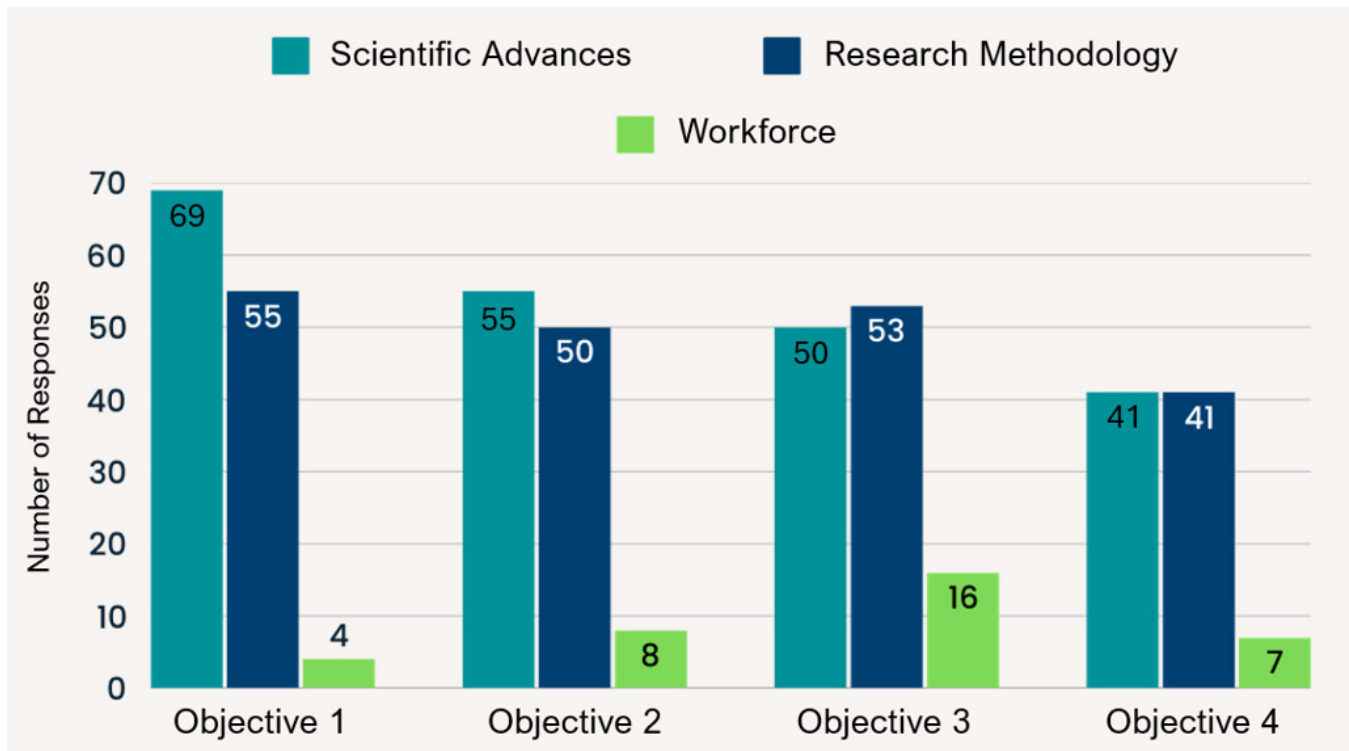


Figure 2. Three overarching themes (Scientific Advances, Research Methodology, and Workforce) emerged across the four RFI objectives.

Scientific Advances

Respondents emphasized the importance of examining fundamental mechanisms and improving diagnostics, treatments, and management options for autoimmune diseases. Responses discussed the need for epidemiologic studies and the use of advanced data analytics and data science. A better understanding of risk factors and opportunities for prevention of autoimmune diseases were also highlighted. Scientific advances were most emphasized in responses to Objective 1, but greater than 80% of responses in the remaining objectives also underscored the importance of advancing the science of autoimmune disease research.

Research Methodology

Respondents noted the importance of examining co-occurring autoimmune diseases and comorbid conditions as well as commonalities across disparate autoimmune diseases. Respondents observed that collaborative research efforts across NIH and with external partners would be essential to improve outcomes for all people living with autoimmune diseases. The Research Methodology theme was emphasized across all objectives, with close to 80% of responses addressing this theme.

Workforce

Although less commonly addressed, respondents also touched on the importance of workforce development, noting the need for a strong, interdisciplinary scientific workforce as well as health care provider and patient education. Workforce was most discussed under Objective 3, appearing in roughly 25% of responses.

Common Topics Within Themes

Across the three overarching themes, responses were further grouped into six common topics. Many of the topics overlapped with several themes, underscoring the need for a strategic approach to autoimmune disease research that dovetails advances in science and research methodology with workforce needs as the field evolves (Figure 3).

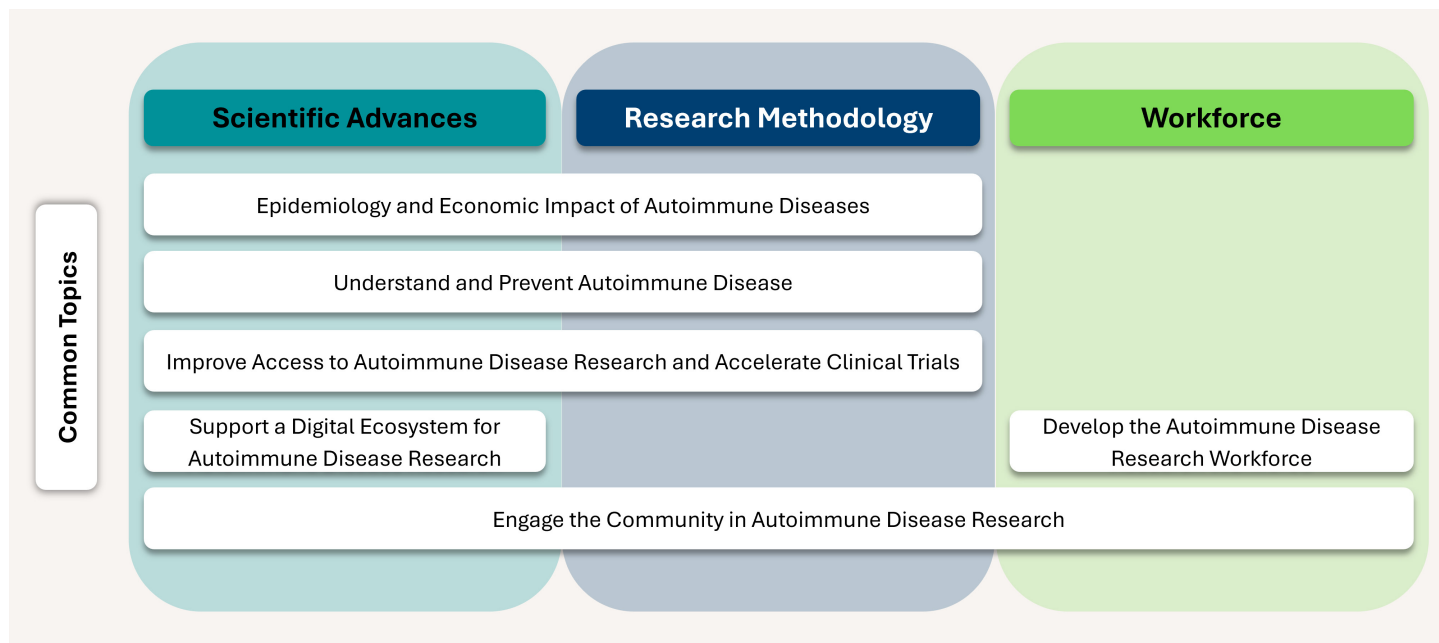


Figure 3. Alignment of six commonly mentioned topics across the three overarching themes identified from the RFI responses.

Highlights from the Community Response

The voice of the autoimmune disease community, including people living with and at risk of autoimmune disease, as well as scientists and researchers who help to study these diseases, was woven throughout the responses. Selected quotes that represent the scope of these responses are provided within each of these topic areas in the following sections.

Epidemiology and Economic Impact of Autoimmune Diseases

Several respondents emphasized the importance of improving understanding of the epidemiology and economic impact of autoimmune diseases. Respondents highlighted the many existing but distributed repositories that exist for autoimmune disease research and the value of supporting core infrastructure that will enable full realization of these resources.

“To understand the economic impact of autoimmune disease, to include work hours lost, health care costs, lost opportunity and burdens on caregivers, family, and children. The long-range implications must be demonstrated, as autoimmune disease is an epidemic, steadily increasing each year.”

“Research [is needed] to understand the role of the collective/combined effects of multiple exposures in the environment to make people susceptible to autoimmune diseases—including the food environment and exposures through lungs and skin.”

“Understanding the genomic, metabolomic, proteomic, microbiomic, environmental exposures...that drive a single individual to develop one or two, but not other, autoimmune diseases will help to identify new therapeutics and intervention strategies.”

“Improving outcomes for all people living with autoimmune diseases is an area of high priority. To do so, it is first necessary to gain a comprehensive understanding of the prevalence of autoimmune diseases across all populations and geographical areas.”

“Combining established cohorts, supporting across disciplinary cohorts, and supporting core resources for investigators from different specialties to utilize.”

“Public health surveillance and descriptive epidemiology, as well as population-based, longitudinal studies: This type of epidemiologic work is fundamental to understanding disease etiology, patterns, burden, etc.”

“Current information is based on relatively small, regional cohorts and extrapolation to the rest of the patient population; modernized information gathering and epidemiological research on general and district patient populations and disease subtypes is greatly needed to inform and instruct research at all levels.”

“Prioritize the use and maintenance of accurate information on the prevalence of autoimmune diseases in the U.S., and the demographics of those who suffer from them.”

Understand and Prevent Autoimmune Disease

Promoting fundamental scientific advances to understand the drivers of autoimmune disease, the autoimmune prodrome, and the presence of co-occurring autoimmune diseases was another important theme. Several respondents highlighted the importance of focusing on immunophenotypes to provide a window into pathways for preventing autoimmunity.

“Programs focused on studying immunophenotypes rather than just disease types might be more scientifically beneficial.”

“Developing an initiative focused on autoimmune disease prevention through population or focused screening for risk.”

“Subclinical or preclinical disease: Understanding earlier markers for disease and their predictive value or ability to be modulated is important for development of screening and prevention strategies and offers etiologic clues.”

“Large scale periodic testing to monitor the early development of autoimmune disease. This requires a more centralized approach to regular collection of blood samples beginning at an early age.”

“...autoimmune diseases are often addressed by physicians of different specialties. Similarly, research is conducted by investigators from different departments and with different methodologic expertise. Processes, programs, and funding that encourage collaboration, both clinically and from a research standpoint, would be fruitful and important.”

“Instead of just researching one ...[autoimmune diseases] need to be researched as a whole, so we can figure out how someone like me doesn't have to go from endometriosis to Hashimoto to RA to Sjogren's to demyelinating polyneuropathy to stiff person syndrome to myasthenia gravis and before you know it, you have so many things wrong. Your whole body is out of control not just one disease.”

“Potential connections between autoimmune diseases and cancers. For instance, some data suggest autoimmune diseases may be associated with improved survival in ovarian cancer...Another example is the use of immune checkpoint inhibitors which are beneficial in cancer but may induce autoimmune features...”

Improve Access to Autoimmune Disease Research and Accelerate Clinical Trials

The importance of improving access to autoimmune disease research was emphasized in many responses, as well as an urgent need to facilitate the successful design and execution of clinical trials for autoimmune disease research.

“Life-course studies and clinical trials for the treatment of autoimmunity that include identifying efficacy and safety of starting and/or extending immunological treatments at both ends of life [in utero and late life/older adults].”

“Research across the spectrum of pediatric rheumatic and other autoimmune diseases remains under-represented and under-funded across the biomedical research enterprise. Particularly relevant to clinical research, most therapies for children and adolescents with autoimmune diseases are based upon very limited knowledge of safety and long-term outcomes of treatments. Moreover, advancements in treatment of pediatric [autoimmune diseases] typically lag years behind their adult counterparts.”

“Autoimmune disease presentations are often more severe in childhood. It can be challenging to study the long-term outcomes of pediatric-onset diseases and the interaction of a potentially stronger genetic influence, maturing immune system and early environmental exposures, along with the lack of confounding comorbidities, provide a unique opportunity to further understand autoimmune disease pathophysiology to the benefit of both children and adults.”

“Although we live in a time of great innovation...failing to ensure that clinical trials are accessible...will mean this innovation will not translate to improved health outcomes for all Americans.”

“Fatigue is a dominant feature of many autoimmune diseases... streamline this research to better understand its broader etiology.”

Support a Digital Ecosystem for Autoimmune Disease Research

Data drive the future of autoimmune disease research, and several respondents emphasized the importance of prioritizing the development of a digital ecosystem as well as data science and computational tools to accelerate autoimmune disease research.

“Establish a standard reference for the terms and terminology to identify core information and eliminate ambiguity of terms. Establish stakeholder consensus for key data elements, primary keys, and overall data structure.”

“...embrace a federated governance structure that supports wide-ranging collaboration without necessitating centralized data, thus preserving each entity’s independence while fostering data sharing and collective research endeavors.”

“...a sophisticated, federated IT architecture utilizing advanced, web-based application programming interfaces (APIs), semantic metadata capabilities (metadata API), and containerized, cloud-based, secure collaborative workspaces.”

“New research opportunities should aim to bring together investigators from fundamental biology to translational and clinical research to epidemiology, and utilize data science, bioinformatics, AI, and machine learning. Drug discovery and in silico design of novel targeted drugs is an example of an area in which NIH should promote interdisciplinary collaborations and initiatives, particularly between fundamental immunologists and computational biologists utilizing AI/machine learning.”

Develop the Autoimmune Disease Research Workforce

Efforts to support and sustain the scientific workforce were also identified by several respondents as a priority that should be included in the development of an *NIH-Wide Strategic Plan for Autoimmune Disease Research*.

“Opportunities to advance interdisciplinary research should involve the levels of training and training grants from predoctoral, doctoral, early, and established career levels. The idea of engaging as a predoctoral fellow to building interdisciplinary teams can help careers start earlier with this emerging skill.”

“...Legitimize PANS/PANDAS as a form of autoimmune encephalitis and to educate medical practitioners so that they can recognize and diagnose PANS/PANDAS in their patients.”

“Develop educational programs to reach and support medical students, residents, and young investigators to ensure a pipeline of experts.”

“Training opportunities, such as Institutional Training Grants and Continuing Education Training Grants, can be developed to train autoimmune researchers to use these (alternative, non-animal) human-relevant systems.”

Engage the Community in Autoimmune Disease Research

Throughout the RFI responses, the importance of community engagement in research planning and clinical trial efforts was emphasized, from leveraging public–private partnerships to collaborating with people living with and at risk for autoimmune disease, patient advocacy groups, and caregivers.

“Patient engagement throughout the research process is critical.”

“Leverage the resources and expertise of the autoimmune patient advocacy community to survey, assess, and communicate with patients.”

“Incorporation of patients, their care givers, patient organizations ... from varied clinical and research settings in all stages of research planning.”

“Provide opportunities for research collaborations and meetings across autoimmune diseases organizations and research groups to identify and address key questions.”

“Work through the various patient advocacy organizations to participate in a large, comprehensive campaign that will focus on education and empowerment for the future of research.”

“Our individual non-profit advocacy groups cannot tackle such a major initiative on our own, but we can partner with NIH leveraging our immense resources to engage communities and improve participation through regular forums for engagement that build trust and credibility in ongoing research and clinical trials.”

Conclusion

The RFI responses summarized here were incorporated into the development of the inaugural *NIH-Wide Strategic Plan for Autoimmune Disease Research*. OADR-ORWH is very grateful to everyone who took the time to provide candid and thoughtful input in response to this initiative.

For more information on the *NIH-Wide Strategic Plan for Autoimmune Disease Research*, visit our website at
<https://orwh.od.nih.gov/OADR-ORWH/Strategic-Planning-for-ADR>



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