National Institutes of Health

NIH-WIDE STRATEGIC PLAN FOR AUTOIMMUNE DISEASE RESEARCH

FISCAL YEARS
2026–2030

NIH-Wide Strategic Plan for Autoimmune Disease Research

Victoria Shanmugam, MBBS, FRCP, FACR, CCD

Coordinating Committee for Autoimmune Disease Research

NIH-WIDE STRATEGIC PLAN FOR AUTOIMMUNE DISEASE RESEARCH

Opening Remarks

Jay Bhattacharya, M.D., Ph.D.

Director, National Institutes of Health

NIH-WIDE STRATEGIC PLAN FOR AUTOIMMUNE DISEASE RESEARCH

NIH-Wide Strategic Plan for Autoimmune Disease

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NIH-WIDE STRATEGIC PLAN FOR AUTOIMMUNE DISEASE RESEARCH

The Office of Autoimmune Disease Research

Aligned with content from the 2022 NASEM Report, Congress directed NIH to establish the Office of Autoimmune Disease Research in the Office of Research on Women's Health.

P.L. 117-328 Consolidated Appropriations Act of 2023 directed OADR-ORWH to:

1. Coordinate development of multi-Institute and Center (IC) strategic research plan
2. Identify emerging areas of innovation and research opportunity
3. Coordinate and foster collaborative research across ICs
4. Annually evaluate NIH Autoimmune Disease Research (ADR) portfolio
5. Provide resources to support planning, collaboration, and innovation
6. Develop publicly accessible central repository for ADR

P.L. 117-328 Consolidated Appropriations Act of 2023

Division H--Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2023

https://nap.nationalacademies.org/catalog/26554/enhancing-nih-research-on-autoimmune-disease

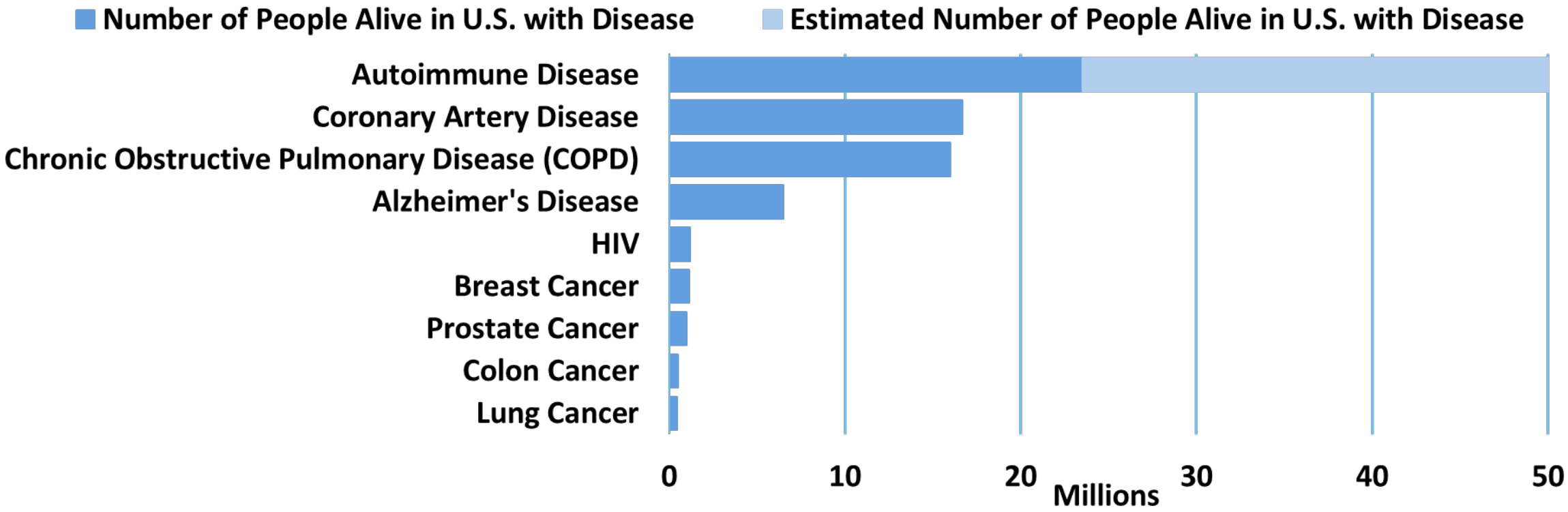
https://orwh.od.nih.gov/OADR-ORWH/ADR-Across-NIH

National Institutes of Health
Office of Autoimmune Disease Research
Office of Research on Women's Health

Fiscal Years 2026 —through— 2030

NIH-WIDE STRATEGIC PLAN FOR AUTOIMMUNE DISEASE RESEARCH

Autoimmune Disease Prevalence in US



https://gis.cdc.gov/Cancer/USCS/#/NationalPrevalence
Santo L, Schappert SM, Ward BW. NCHS Data Brief, no 510. Hyattsville, MD: National Center for Health Statistics. DOI: https://dx.doi.org/10.15620/cdc/164015
https://www.cdc.gov/hiv-data/nhss/estimated-hiv-incidence-and-prevalence.html
https://www.cdc.gov/cdi/indicator-definitions/chronic-obstructive-pulmonary-disease.html
https://www.cdc.gov/heart-disease/data-research/facts-stats/index.html
https://ehp.niehs.nih.gov/doi/10.1289/ehp.119-a248

USCS U.S. Cancer Statistics
The Official Federal Cancer Statistics

Fiscal Years 2026 —through— 2030

NIH-WIDE STRATEGIC PLAN FOR AUTOIMMUNE DISEASE RESEARCH

The mission of the *NIH-Wide Strategic Plan for Autoimmune Disease Research* is to coordinate and advance efforts to support rigorous, high-priority, innovative, and collaborative autoimmune disease research.

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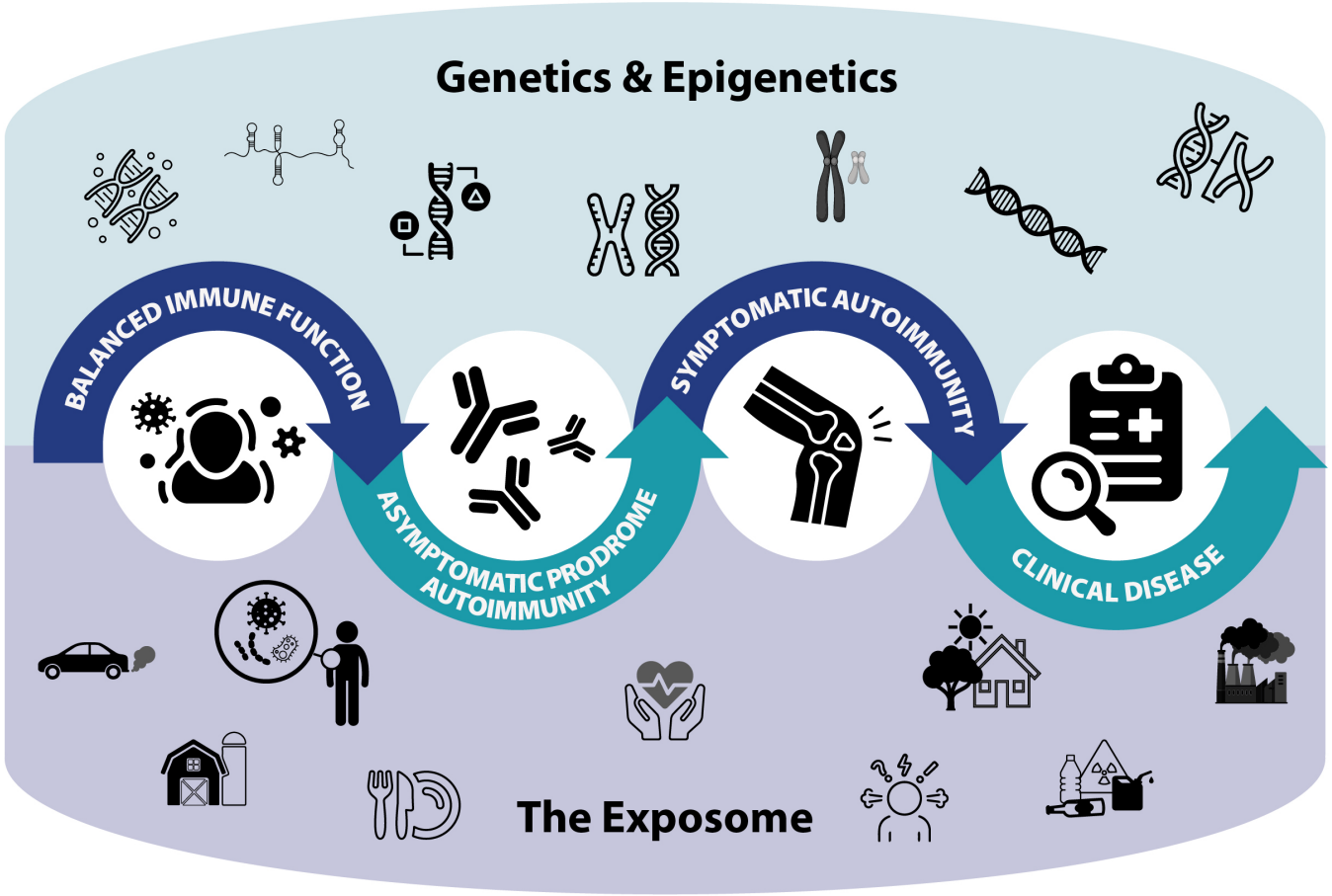
NIH-WIDE STRATEGIC PLAN FOR AUTOIMMUNE DISEASE RESEARCH

Autoimmune Prodrome



NIH-WIDE STRATEGIC PLAN FOR AUTOIMMUNE DISEASE RESEARCH

Exposome and Autoimmunity

Physical Environment

The human immune response can be affected by UV light, radiation, pesticides, atmospheric dust, water and soil impurities, chemical exposures at home and work, as well as the surrounding natural environment.

Social Environment and Lifestyle

Diet, exercise, sleep habits, stress, smoking, and alcohol and drug use, along with socioeconomic conditions, may also influence the human immune response.

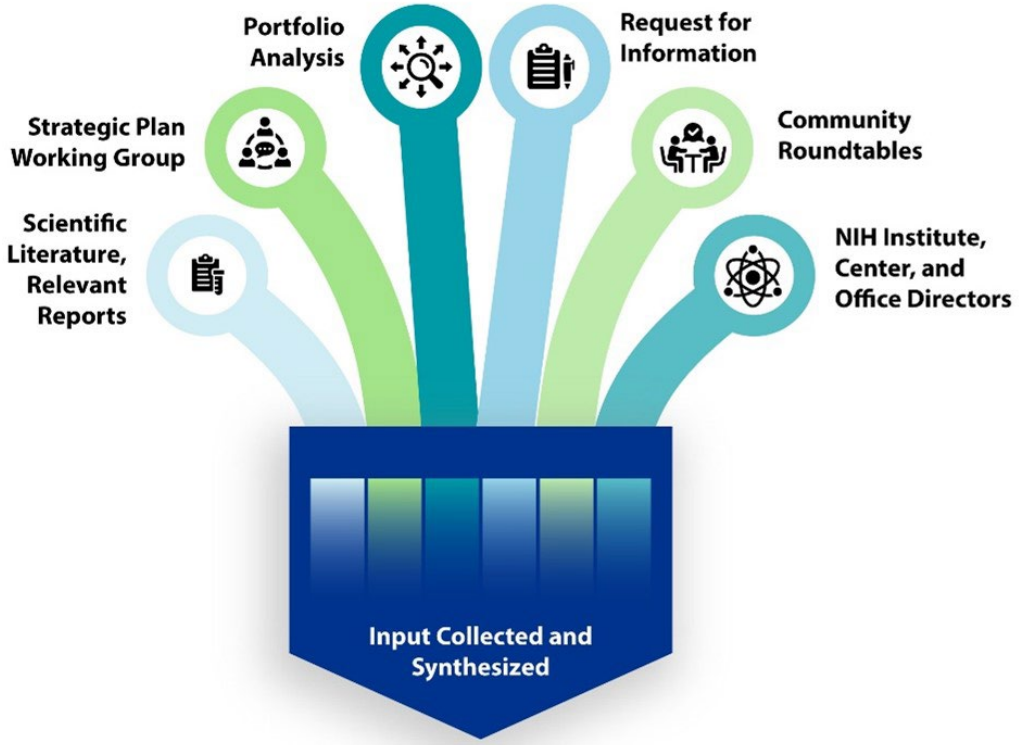
Biologic Pathways

Environmental exposures can cause biological changes that affect DNA, protein levels, signaling pathways, and metabolism, all of which can result in immunologic changes.

*Figure adapted from the National Institute of Environmental Health Sciences (NIEHS)

NIH-WIDE STRATEGIC PLAN FOR AUTOIMMUNE DISEASE RESEARCH

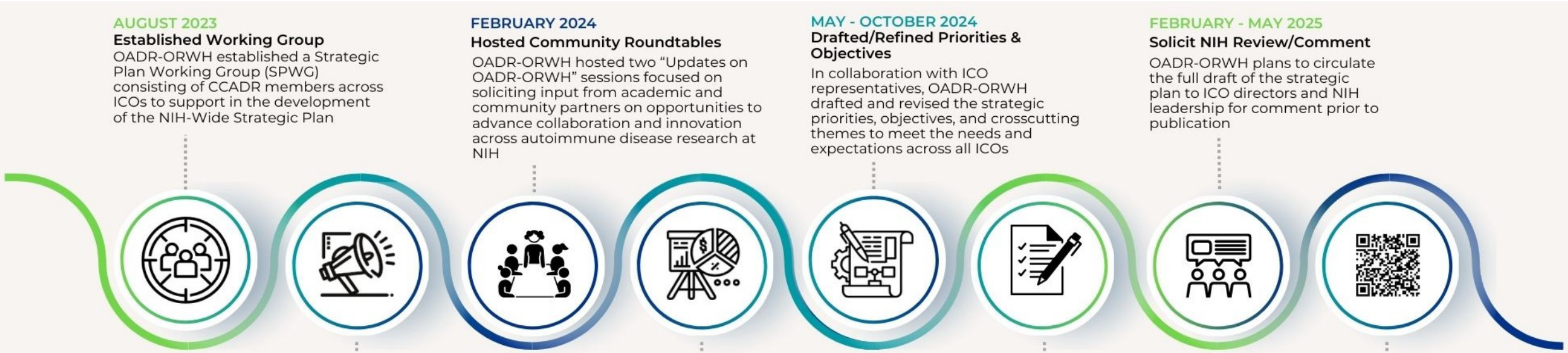
Priority Setting and Strategic Planning Process



Fiscal Years 2026 —through— 2030

NIH-WIDE STRATEGIC PLAN FOR AUTOIMMUNE DISEASE RESEARCH

Timeline of Key Milestones



AUGUST 2023
Established Working Group
OADR-ORWH established a Strategic Plan Working Group (SPWG) consisting of CCADR members across ICOs to support in the development of the NIH-Wide Strategic Plan

DECEMBER 2023
Published RFI
OADR-ORWH requested input from members of the scientific community, federal partners, academic institutions, the private sector, health professionals, professional societies, advocacy groups, patient communities, and other interested members of the public

FEBRUARY 2024
Hosted Community Roundtables
OADR-ORWH hosted two "Updates on OADR-ORWH" sessions focused on soliciting input from academic and community partners on opportunities to advance collaboration and innovation across autoimmune disease research at NIH

APRIL 2024
Conducted Portfolio Analysis
OADR-ORWH curated a comprehensive autoimmune disease portfolio to include awards across more than 140 diseases and conditions. This ongoing analysis provided data-driven insights to support the development of strategic priorities and objectives

MAY - OCTOBER 2024
Drafted/Refined Priorities & Objectives
In collaboration with ICO representatives, OADR-ORWH drafted and revised the strategic priorities, objectives, and crosscutting themes to meet the needs and expectations across all ICOs

DECEMBER 2024
Complete Final Draft
OADR-ORWH is actively working to finalize the draft of the *NIH-Wide Strategic Plan for Autoimmune Disease Research*, aiming for completion by December 2024

FEBRUARY - MAY 2025
Solicit NIH Review/Comment
OADR-ORWH plans to circulate the full draft of the strategic plan to ICO directors and NIH leadership for comment prior to publication

END OF FISCAL YEAR 2025
Publish
OADR-ORWH aims to publish and promote the *NIH-Wide Strategic Plan for Autoimmune Disease Research* by the end of FY25. Publication will be available at: https://orwh.od.nih.gov/OADR-ORWH/Strategic-Planning-for-ADR

NIH-WIDE STRATEGIC PLAN FOR AUTOIMMUNE DISEASE RESEARCH

Request for Information: Inviting Input NIH-Wide Strategic Plan for Autoimmune Disease Research

- December 2023 - developed and issued a Request for Information (RFI, NOT-OD-24-049) inviting input on the development of an NIH-wide strategic plan to advance autoimmune disease research.

- OADR-ORWH also hosted two virtual community roundtable discussions in February 2024 to garner additional insights from academic and patient advocacy partners.

https://orwh.od.nih.gov/OADR-ORWH/Strategic-Planning-for-ADR

SUMMARY OF RFI RESPONSES

Objective 1:
Research areas for cross-cutting collaborative research
70 Responses

Objective 2:
Opportunities to advance collaborative, innovative, or interdisciplinary areas of autoimmune disease research
63 Responses

Objective 3:
Opportunities to improve outcomes for individuals with autoimmune diseases
62 Responses

Objective 4:
Cross-cutting areas integral to advancing autoimmune disease research
47 Responses

NIH-WIDE STRATEGIC PLAN FOR AUTOIMMUNE DISEASE RESEARCH

Selected Quotes from RFI

> Research to understand the role of the collective/combined effects of multiple exposures in the environment to make people susceptible to autoimmune diseases.

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

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

> 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.

2022 NASEM REPORT

OPPORTUNITIES FOR ENHANCING AUTOIMMUNE DISEASE RESEARCH

OPPORTUNITY 1

Establish an Office of Autoimmune Disease/Autoimmunity Research within the Office of the Director at the NIH.

OPPORTUNITY 2

Establish long-term systems to collect and ensure optimum usability of population-based surveillance and epidemiological data (e.g., incidence, prevalence) on autoimmune diseases and measures of autoimmunity (e.g., autoantibodies, inflammation) and support the optimization of existing data sources.

OPPORTUNITY 3

Development of population cohorts that extend from the period before disease manifests to the development of symptoms and disease and should support patient cohorts that will allow the examination of the progression, coexisting morbidities, and long term (20+ years) outcomes of autoimmune diseases. Data collection should include, but need not be limited to:

- Genome wide association
- Environmental/Occupational Exposures
- Autoantibody, cytokine, T cell assays
- Response to therapy
- Development of co-occurring autoimmune disease

OPPORTUNITY 4

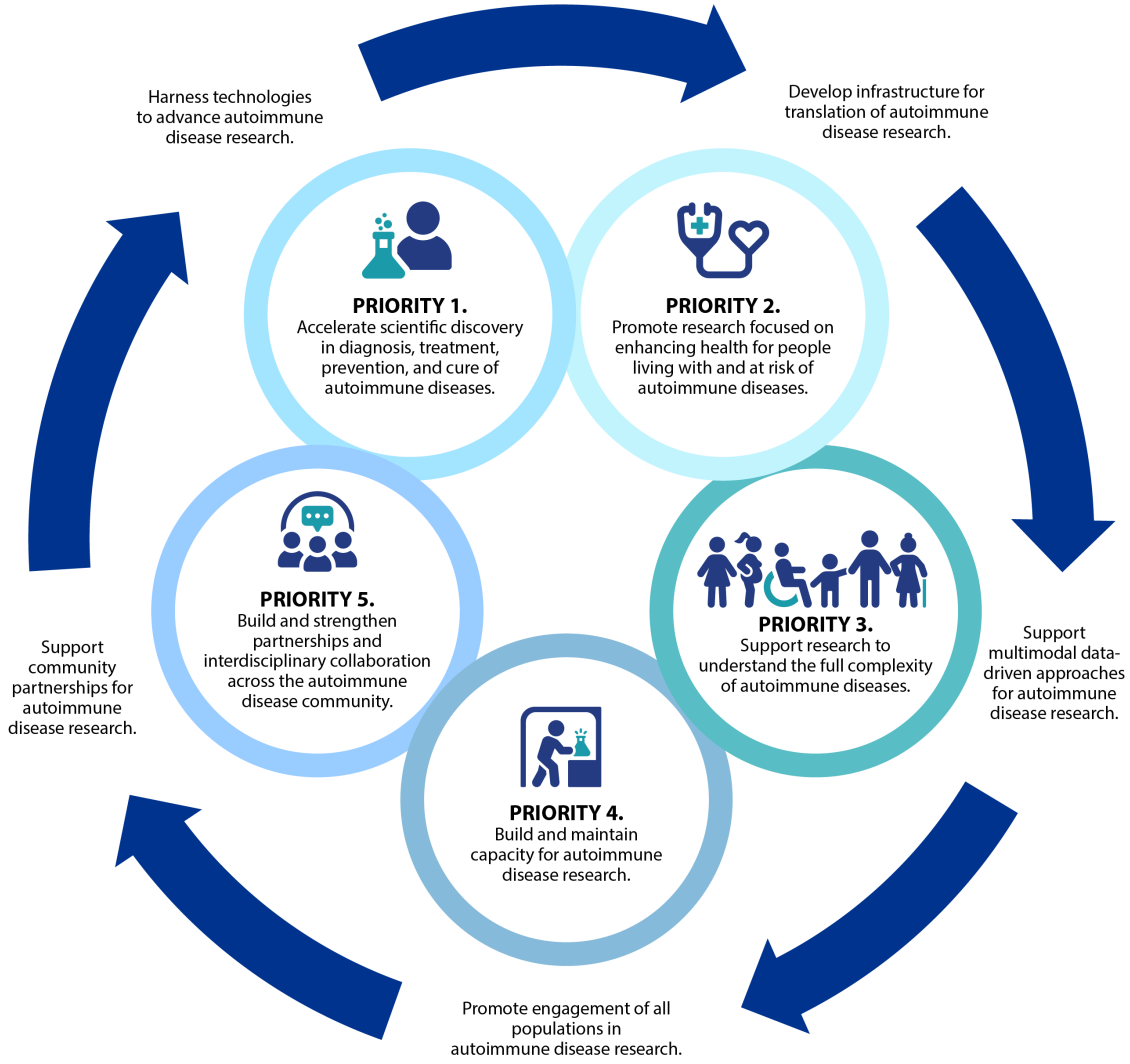
Provide funding and support for a national autoimmune disease research agenda that addresses key gaps identified by the committee. Prioritized research streams should include, but need not be limited to, clinical and basic research that addresses the research streams:

- Common and disease-specific pathogenic mechanisms
- Rare autoimmune diseases and animal models
- Autoantibodies and biomarkers that predict progression
- Genetic variants and gene-environment interactions
- Environmental exposures and social determinants of health across lifespan
- Impact of coexisting morbidities and complications
- Health equity for all autoimmune disease patients
- Assess the direct and indirect costs of autoimmune diseases

https://nap.nationalacademies.org/catalog/26554/enhancing-nih-research-on-autoimmune-disease

Fiscal Years 2026 —through— 2030

NIH-WIDE STRATEGIC PLAN FOR AUTOIMMUNE DISEASE RESEARCH



Fiscal Years 2026 —through— 2030

NIH-WIDE STRATEGIC PLAN FOR AUTOIMMUNE DISEASE RESEARCH

PRIORITY 1: Accelerate scientific discovery in diagnosis, treatment, prevention, and cure of autoimmune diseases.

OBJECTIVE 1.1	**Support research into fundamental mechanisms of autoimmunity and autoimmune disease.**
OBJECTIVE 1.2	**Advance understanding of drivers of autoimmune disease signs, symptoms, and flares.**
OBJECTIVE 1.3	**Optimize development of research models for studying autoimmune disease.**
OBJECTIVE 1.4	**Improve understanding of predictors and risk factors for autoimmunity across the lifespan.**

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NIH-WIDE STRATEGIC PLAN FOR AUTOIMMUNE DISEASE RESEARCH

PRIORITY 2: Promote research focused on enhancing health for people living with and at risk of autoimmune diseases.

OBJECTIVE 2.1 Support research investigating preclinical autoimmunity.

OBJECTIVE 2.2 Advance research to accelerate accurate diagnosis of autoimmune disease.

OBJECTIVE 2.3 Bolster research focused on improving treatment for autoimmune disease.

OBJECTIVE 2.4 Support implementation science for autoimmune disease research across all populations.

NIH-WIDE STRATEGIC PLAN FOR AUTOIMMUNE DISEASE RESEARCH

PRIORITY 3: Support research to understand the full complexity of autoimmune diseases.

OBJECTIVE 3.1 Support the study of human cohorts for autoimmune disease research.

OBJECTIVE 3.2 Promote research to understand how different populations are affected by autoimmune diseases.

OBJECTIVE 3.3 Advance research that will facilitate clinical trials for autoimmune diseases.

OBJECTIVE 3.4 Expand autoimmune disease research focused on co-occurring and comorbid conditions.

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NIH-WIDE STRATEGIC PLAN FOR AUTOIMMUNE DISEASE RESEARCH

PRIORITY 4: Build and maintain capacity for autoimmune disease research.

OBJECTIVE 4.1 Prioritize and support development of infrastructure for autoimmune disease research.

OBJECTIVE 4.2 Integrate clinical trial networks and registries in autoimmune disease research.

OBJECTIVE 4.3 Develop data science and computational tools to accelerate autoimmune disease research.

OBJECTIVE 4.4 Support efforts to develop and sustain the scientific workforce.

NIH-WIDE STRATEGIC PLAN FOR AUTOIMMUNE DISEASE RESEARCH

PRIORITY 5: Build and strengthen partnerships and interdisciplinary collaboration across the autoimmune disease community.

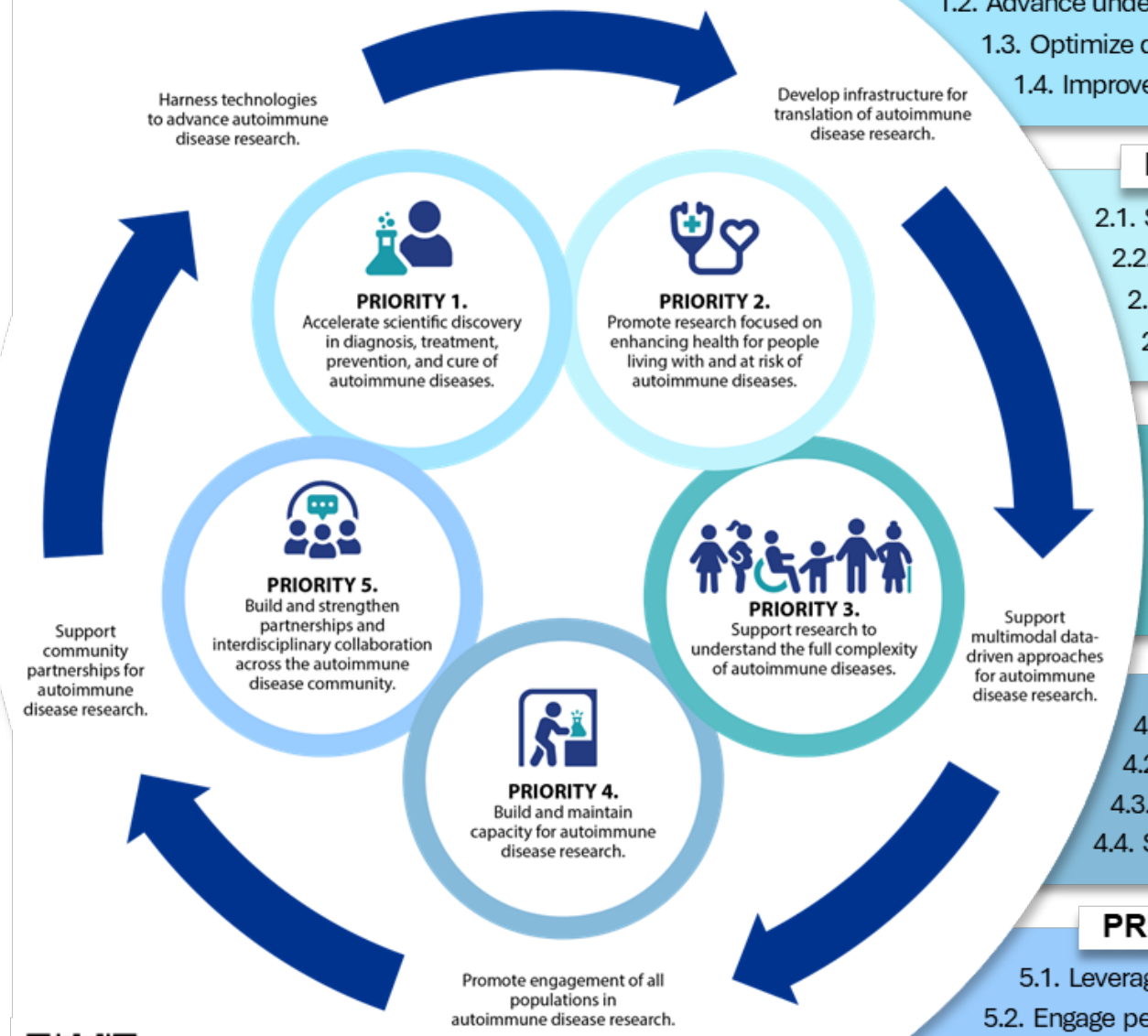
OBJECTIVE 5.1	**Leverage public–private partnerships to support autoimmune disease research.**
OBJECTIVE 5.2	**Engage people living with autoimmune diseases, patient advocacy groups, and caregivers in research.**
OBJECTIVE 5.3	**Partner with people and communities disproportionately affected by autoimmune disease outcomes.**
OBJECTIVE 5.4	**Coordinate and foster collaborative research.**

NIH-WIDE STRATEGIC PLAN FOR AUTOIMMUNE DISEASE RESEARCH

Crosscutting Themes

1. Harness technologies to advance autoimmune disease research.
2. Develop infrastructure for translation of autoimmune disease research.
3. Support multimodal data-driven approaches for autoimmune disease research.
4. Promote engagement of all populations in autoimmune disease research.
5. Support community partnerships for autoimmune disease research.

Strategic Priorities & Objectives



Read the detailed plan online:
https://orwh.od.nih.gov/OADR-ORWH/Strategic-Planning-for-ADR

PRIORITY 1

1.1. Support research into fundamental mechanisms of autoimmunity and autoimmune disease
1.2. Advance understanding of drivers of autoimmune disease signs, symptoms, and flares
1.3. Optimize development of research models for studying autoimmune disease
1.4. Improve understanding of predictors and risk factors for autoimmunity across the lifespan

PRIORITY 2

2.1. Support research investigating preclinical autoimmunity
2.2. Advance research to accelerate accurate diagnosis of autoimmune disease
2.3. Bolster research focused on improving treatment for autoimmune disease
2.4. Support implementation science for autoimmune disease research across all populations

PRIORITY 3

3.1. Support the study of human cohorts for autoimmune disease research
3.2. Promote research to understand how different populations are affected by autoimmune diseases
3.3. Advance research that will facilitate clinical trials for autoimmune diseases
3.4. Expand autoimmune disease research focused on co-occurring and comorbid conditions

PRIORITY 4

4.1. Prioritize and support development of infrastructure for autoimmune disease research
4.2. Integrate clinical trial networks and registries in autoimmune disease research
4.3. Develop data science and computational tools to accelerate autoimmune disease research
4.4. Support efforts to develop and sustain the scientific workforce

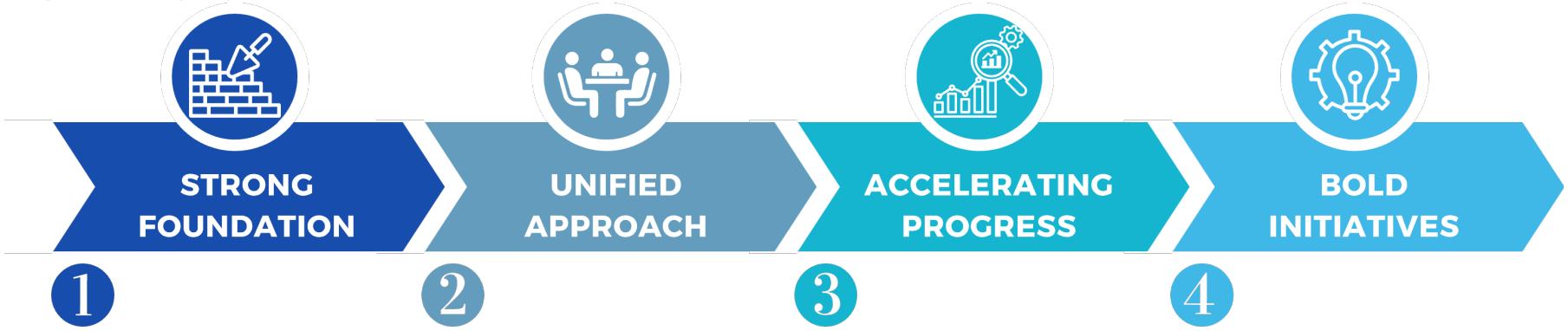
PRIORITY 5

5.1. Leverage public–private partnerships to support autoimmune disease research
5.2. Engage people living with autoimmune diseases, patient advocacy groups, and caregivers in research
5.3. Partner with people and communities disproportionately affected by autoimmune disease outcomes
5.4. Coordinate and foster collaborative research

Fiscal Years 2026 —through— 2030

NIH-WIDE STRATEGIC PLAN FOR AUTOIMMUNE DISEASE RESEARCH

Implementation Vision



1

EXISTING PROGRAMS AND RESEARCH

Autoimmune disease research intersects with the mission areas of each NIH Institute and Center. Building on the strong foundation of existing programs will be crucial to advance the agenda for autoimmune disease research.

2

AN NIH-WIDE STRATEGIC PLAN

Synergizing efforts across NIH through coordinated development of Requests for Applications, Program Announcements, and other similar mechanisms will ensure efficient execution of the *NIH-Wide Strategic Plan for Autoimmune Disease Research*.

3

NOVEL RESEARCH AND PARTNERSHIPS

Building on existing and developing new public–private partnerships will be critical to accelerate the autoimmune disease research agenda and de-risk cutting-edge biomedical science, ensuring maximum return on investment to accelerate research and discovery for all people living with autoimmune diseases.

4

REACHING TOWARD A HEALTHIER FUTURE

Developing a scalable federated data infrastructure, investing in longitudinal immunophenotyping repositories, and supporting the research pipeline and biomedical workforce through a national network of autoimmune centers are some of the bold opportunities that will accelerate autoimmune disease research to meet the needs of all people living with and at risk for autoimmune diseases.

NIH-WIDE STRATEGIC PLAN FOR AUTOIMMUNE DISEASE RESEARCH

THANK YOU! Strategic Plan Working Group Members

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NIH-WIDE STRATEGIC PLAN FOR AUTOIMMUNE DISEASE RESEARCH

THANK YOU

Access the full strategic plan online:
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NIH-WIDE STRATEGIC PLAN FOR AUTOIMMUNE DISEASE RESEARCH

Closing Remarks

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Director, Office of Research on Women's Health

National Institutes of Health

NIH-WIDE STRATEGIC PLAN FOR AUTOIMMUNE DISEASE RESEARCH

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