

May 26, 2026

Dr. Jay Bhattacharya  
Director  
National Institutes of Health (NIH)  
9000 Rockville Pike  
Bethesda, MD 20892



**RE: Request for Information (RFI) on the National Institutes of Health (NIH)-Wide Strategic Plan for Fiscal Years 2027-2031 (NOT-OD-26-047)**

Dear Dr. Bhattacharya,

The Lupus Foundation of America (LFA) welcomes the opportunity to submit comments on the Framework for the NIH-Wide Strategic Plan for Fiscal Years 2027–2031. As NIH develops this framework, it is essential that the agency fully utilize funds appropriated by Congress each year, ensure timely grant funding, and maintain a robust research portfolio that does not limit the number of grants available by arbitrarily expanding obligations for multi-year awards.

**Priority 1: Research Areas**

- Goal 1: Advance Foundational Knowledge of Human Health and Disease
- Goal 2: Prevent Disease and Promote Health Across the Lifespan
- Goal 3: Advance and Optimize Interventions, Treatments, and Cures

**Goal 1: Advance Foundational Knowledge of Human Health and Disease**

NIH should prioritize a deeper understanding of lupus to address its biological complexity and heterogeneity. Increased investment in basic and translational research is needed to identify mechanisms driving autoimmunity, inflammation, and organ damage. NIH should strengthen and harmonize large-scale longitudinal cohort studies integrating genomics, proteomics, metabolomics, and environmental exposure data to support data sharing and discovery.

NIH should also support infrastructure linking lupus cohorts with claims data, hospitalization records, mortality data, and other public health sources. These datasets are critical for understanding severe outcomes such as end-stage kidney disease, cardiovascular disease, disability, hospitalization, and premature mortality. Research must address disease variability, including why lupus disproportionately affects women and Black, Hispanic/Latino, Asian, and Indigenous populations. NIH should lead efforts to develop and validate biomarkers for early detection, disease activity, and prognosis. Investments in data infrastructure, interoperability, and artificial intelligence will further accelerate discovery and collaboration.

**Goal 2: Prevent Disease and Promote Health Across the Lifespan**

NIH should expand research on prevention, early diagnosis, and reducing barriers to care in lupus. Priorities include predictive risk models that integrate genetic susceptibility,

environmental exposures, and clinical indicators to identify individuals at high risk for lupus or severe disease. NIH-supported studies should examine modifiable risk factors—including environmental toxins, infections, stress, and social determinants of health—and evaluate interventions to reduce their impact.

Improving early diagnosis is critical. NIH should support development of screening tools, clinical decision support systems, and implementation research to improve recognition and referral pathways in primary care, emergency departments, community health systems, and underserved settings. Research should also address care across the lifespan, including pediatric-onset lupus, transition to adult care, and aging with lupus. Community-engaged research and implementation science should ensure prevention and health promotion strategies are culturally appropriate, effective, and accessible.

### **Goal 3: Advance and Optimize Interventions, Treatments, and Cures**

NIH plays a vital role in accelerating lupus therapies. Priorities should include innovative clinical trial designs, such as adaptive and platform trials, that evaluate multiple therapies efficiently while reflecting the lupus population predominantly impacted. NIH should promote validated biomarkers and surrogate endpoints to streamline trials and reduce time to approval. Expanding precision medicine research will support more targeted and effective treatments.

NIH should also invest in compassionate comparative effectiveness research and real-world evidence to optimize existing therapies and improve long-term outcomes. Increasing trial accessibility and participation among populations most impacted by lupus must remain a priority through community partnerships and decentralized trial models. Finally, NIH should support research on care delivery, including strategies to improve care coordination, medication adherence, and multidisciplinary care, ensuring scientific advances translate into better patient outcomes.

### **Priority 2: Research Capacity**

- Goal 1: Develop and Sustain an Interdisciplinary Research Workforce
- Goal 2: Build, Improve, and Sustain Research Resources and Infrastructure

### **Goal 1: Develop and Sustain an Interdisciplinary Research Workforce**

NIH should prioritize building a diverse, interdisciplinary lupus research workforce that spans basic science, clinical investigation, population health, and data science. This begins with expanding targeted training and career development programs (e.g., K- and T-awards) that specifically support early-career investigators entering lupus and autoimmune disease research. Dedicated funding opportunities and loan repayment incentives can help attract talent from complementary disciplines.

To sustain the workforce, it would be ideal if NIH created structured pathways for collaboration across Institutes and disciplines, including team science grants and cross-Institutional research

networks focused on lupus. Mentorship programs that pair junior investigators with experienced lupus researchers will be critical to retention and advancement.

NIH should also invest in clinician-scientist development by supporting protected research time for rheumatologists and other specialists, addressing a persistent barrier in translational lupus research. Training programs should incorporate emerging skill sets, including artificial intelligence, multi-omics analysis, and community-engaged research methods. Finally, NIH can strengthen the workforce by fostering partnerships with nationally-recognized lupus non-profit patient advocacy organizations and incorporating patient perspectives into training programs, ensuring that research remains patient-centered and relevant.

### **Goal 2: Build, Improve, and Sustain Research Resources and Infrastructure**

NIH should prioritize a modern, integrated research infrastructure that enables collaboration, data sharing, and rapid translation of discoveries into practice. Central to this effort is the expansion and harmonization of lupus cohorts, registries, and biorepositories that capture longitudinal clinical data and biospecimens from diverse populations. Standardized data elements and interoperable systems will allow researchers to combine datasets across studies and Institutes, maximizing the value of NIH investments. In addition, working with organizations and entities that may already have access to datasets that may prove vital to speeding scientific developments.

Investment in advanced data infrastructure is also critical. NIH should support secure, cloud-based platforms that facilitate real-time data sharing, integration of multi-omics datasets, and application of artificial intelligence tools. These platforms should be accessible to investigators across institutions, including those with limited resources, to democratize access to high-quality data and analytic capabilities.

NIH should also strengthen clinical research infrastructure by supporting networks of trial-ready sites with the capacity to conduct innovative, efficient, and inclusive lupus clinical trials. This includes expanding decentralized and community-based research models to reduce barriers to. Infrastructure investments should also support the validation and qualification of biomarkers and endpoints, which are essential for accelerating therapeutic development.

Finally, NIH should invest in implementation and dissemination infrastructure to ensure that research findings are translated into clinical practice. This includes supporting health services research, care delivery models, and digital tools that improve care coordination and patient outcomes.

Together, these recommendations position NIH to build a robust, inclusive, and future-ready research ecosystem capable of advancing lupus science and improving patient outcomes.

### **Priority 3: Research Operations**

- Goal 1: Enhance Scientific Stewardship and Decision-Making
- Goal 2: Foster Transparency and Accountability to Improve Public Trust in Science

#### **Goal 1: Enhance Scientific Stewardship and Decision-Making**

NIH should adopt a more coordinated, data-driven approach to managing lupus research across Institutes and Centers. Given that lupus spans immunology, nephrology, dermatology, cardiology, and other disciplines, NIH should strengthen cross-Institute governance mechanisms—such as the Lupus Federal Working Group—with clear authority to set priorities, align funding, and reduce duplication. Establishing a unified lupus research framework with measurable milestones (e.g., biomarker validation, improved diagnostic timelines, increased trial diversity) would improve accountability and strategic focus. NIH stewardship efforts should prioritize outcomes that matter most to patients, including fatigue, physical functioning, cognitive impairment, ability to work, treatment burden, and health-related quality of life, in addition to traditional disease activity measures. Increased integration of patient-reported outcomes into observational studies and clinical trials will improve the relevance and translational value of lupus research.

Decision-making should be guided by robust portfolio analysis, leveraging real-time data on funded projects, emerging scientific opportunities, and gaps in the field. NIH should invest in analytic tools that assess return on investment, identify underfunded areas (such as health services research or pediatric lupus), and ensure balance across basic, translational, and clinical research. Incorporating patient and clinician input into priority-setting processes—through advisory councils, listening sessions, and participatory research models—will help ensure that funding decisions reflect real-world needs.

NIH should also streamline grant review and funding processes to accelerate high-impact lupus research. This includes piloting faster review pathways for innovative proposals, expanding mechanisms for high-risk/high-reward research, and reducing administrative burden for investigators. Strengthening coordination with other federal agencies and private partners can further leverage resources and avoid fragmentation. Finally, NIH should embed equity considerations into all stewardship decisions, ensuring that research investments address gaps in disease burden, access to care, and outcomes.

#### **Goal 2: Foster Transparency and Accountability to Improve Public Trust in Science**

To build and sustain public trust, NIH should prioritize transparency in how lupus research is funded, conducted, and translated into outcomes. This begins with clear, accessible communication about research priorities, funding decisions, and progress toward goals. NIH should regularly publish lupus-specific portfolio analyses, including data on funding distribution, study populations, and research outcomes, presented in formats that are understandable to patients and the public.

Open science practices should be expanded to ensure that data and findings from NIH-funded lupus research are broadly accessible. This includes timely data sharing through secure, user-friendly platforms; publication of negative as well as positive results; and adherence to standardized reporting guidelines. NIH should also promote transparency in clinical trials by ensuring that protocols, endpoints, and results are publicly available and communicated in plain language summaries.

Accountability can be strengthened through the use of clear performance metrics and public reporting on progress. NIH should track and report indicators such as time to diagnosis, diversity in clinical trial enrollment, and translation of research findings into clinical practice. Engaging patients and community stakeholders can further enhance accountability and trust. By demonstrating openness, responsiveness, and measurable progress, NIH can strengthen public trust while advancing meaningful scientific and clinical gains.