

Lupus ABC

UPDATES

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This semi-annual briefing is designed to update Lupus Accelerating Breakthroughs Consortium (Lupus ABC) members and the broader community on key milestones, new initiatives, and ongoing progress across the consortium. This issue features highlights from the 2026 Lupus ABC Annual Meeting, key accomplishments from Lupus ABC's third year, and other important updates.

As the Lupus ABC enters its fourth year, we extend our sincere gratitude to our partners across the FDA, industry, academia, NIH, nonprofit organizations, and the broader lupus community for their steadfast dedication to this public-private partnership (PPP). We are especially grateful to the Lupus Voices Council members for ensuring that meaningful patient and care partner perspectives are integrated across all working groups. The past year has marked a significant period of progress and maturation for Lupus ABC, which we are pleased to highlight.

"I'm so excited because the science is ready now, and we're poised to make real advancements, breakthroughs, potential remissions or a cure. We have to aim for that. And I'm so excited about the contributions Lupus ABC can make." -Janet Woodcock, M.D., Former Acting Commissioner, FDA

2026 Annual Meeting Highlights

Lupus ABC convened its annual meeting on April 14-15, 2026, in Rockville, Maryland. The gathering marked three years since its launch as the first PPP with the FDA dedicated to accelerating the development of safer and more effective lupus treatments.

Click here to see highlights from the 2026 Annual Meeting, including:

- Working groups' progress
- Personal account of living with lupus by LVC member Cindy Coney
- Keynote address by Rafid Fadul, M.D., MBA CMO and Deputy Director of ARPA-H
- Panel discussion on challenges and opportunities in pediatric lupus clinical trials



Announcements

- Lupus ABC is pleased to announce that Janet Woodcock, M.D., Former Acting FDA Commissioner, has generously accepted to serve as the next Research Committee Co-Chair beginning in 2027.
- Lupus ABC will convene an in-person meeting in 2027 to address the challenges in lupus clinical trial design, a high-priority topic for Lupus ABC since its inception. The planning for this innovative clinical trial design meeting will be led by a planning committee comprised of Lupus ABC members and other external experts.
- Lupus ABC is now accepting nominations of individuals with lived experience to the Lupus Voices Council and academic/non-industry members to the Research Committee for 2027. Please reach out to lupusabc@lupusresearch.org for more information. The deadline for nominations to the LVC is September 4, 2026, and the deadline for nominations to the RC is September 30, 2026.



"You all give us what I consider the greatest gift... You give us the gift of hope."

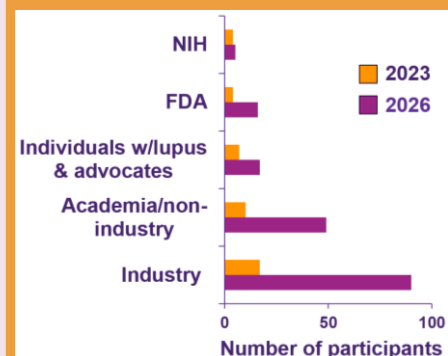
-Cindy Coney, Lupus Voices Council member

Lupus ABC Growth from 2023 to 2026

The number of member organizations, number of WGs and participants in Lupus ABC has increased:

	2023	2026
Member organizations	32	50
Working Groups	1	5
Participants	42	177

The number of participants in working groups has increased across all stakeholder categories:



Lupus ABC Year Three Accomplishments

Five Peer-Reviewed Publications:

1. CLASI outcome measure recommendations (*Nature Reviews Rheumatology*, 2026)
2. Incorporating PROs into lupus trials (*Lupus Science & Medicine*, 2025)
3. Considerations for CAR T-cell therapy for SLE (*RMD Open*, 2025)
4. Lupus ABC collaboration framework (*Nature Reviews Rheumatology*, 2025)
5. TRM-SLE Delphi study (*Lupus Science & Medicine*, 2025)

Working Group (WG) Updates: [\[Read more here\]](#)

- **The CLASI WG** successfully achieved FDA acknowledgment of CLASI 70 as a reasonable outcome measure to measure efficacy in cutaneous lupus erythematosus clinical trials in 2024. It is now analyzing real-world and trial data to define clinically meaningful thresholds for improvement.
- **The Patient Reported Outcomes (PRO) Measures WG** seeks to establish a standardized core set of patient-reported outcome domains and validated instruments for consistent use in lupus clinical trials. Through a structured consensus process, the group narrowed an initial list of 25 domains to seven core domains and is now advancing stakeholder validation and instrument evaluation.
- **The PRO Trial Data WG** aims to evaluate the performance and responsiveness of PRO instruments using existing lupus clinical trial data to inform evidence-based recommendations. The group has identified relevant trials, developed a consensus analysis plan, and begun partnering with industry sponsors to access data and conduct analyses for future meta-analysis.
- **The Immune Reset WG** aims to accelerate the development of immune-resetting therapies in lupus by standardizing definitions, improving data comparability, and aligning biological measurements across emerging treatment modalities. Since early 2026, the group has launched three coordinated subprojects with efforts focused on 1) a data dashboard, 2) consensus-building activities on key definitions, and 3) immune phenotyping.
- **The TRM-SLE Project** aims to develop a novel, domain-based continuous outcome measure that captures clinically meaningful treatment response across organ systems in lupus clinical trials. The group has finalized the instrument and responder definitions after a comprehensive multi-year development process and is now proceeding with validation studies and regulatory engagement to support widespread adoption.

Year Four Activities: New Initiatives and Partnerships

New Lupus ABC Projects:

Lupus ABC launched its first RFP in August 2025 to solicit project ideas from the broad community. We are pleased to announce that the following two projects were selected after a thorough, multi-stakeholder review.

- **STELLAR-Project (Sustained Targets in Evaluating Lupus Low Activity and Remission as Primary Objective)**, led by Christian Stach, M.D., and Megan Lockwood, M.D. This new working group will evaluate novel clinical trial designs for SLE treatments aimed at achieving sustained remission or low disease activity without significant flares.
- Support for the ongoing Advanced Definition of Remission in SLE (DORIS+) initiative, led by Ronald van Vollenhoven, M.D., Ph.D. Building on the work of the international DORIS task force, this project seeks to define an even more profound state of remission in SLE that may now be achievable in lupus and is not adequately captured by prior remission definitions.

New Partnerships:

- Lupus ABC is pleased to welcome the Office of Autoimmune Disease Research within the Office of Research on Women's Health as a Lupus ABC member.



LVC members at the 2026 Lupus ABC Annual Meeting