

Lupus Accelerating Breakthroughs Consortium

REQUEST FOR PROPOSALS

Projects to Address Challenges in Lupus Drug Development

BACKGROUND

Systemic lupus erythematosus (SLE) is a highly complex systemic autoimmune disease characterized by a myriad of clinical features, including skin rashes, arthritis, fatigue, and potentially life-threatening organ damage. The heterogeneity of the disease presents significant challenges in measuring disease activity and assessing drug efficacy, posing substantial obstacles to drug development. In the last seventy years, only three drugs developed specifically for SLE and Lupus Nephritis (LN) have been approved, and none have been approved for primary cutaneous lupus erythematosus (CLE).

Lupus Accelerating Breakthroughs Consortium ([Lupus ABC](#)) was established in 2023 in response to the urgent and unmet medical need for effective lupus therapies. As the only public-private partnership (PPP) with the U.S. Food and Drug Administration (FDA) focused on lupus, Lupus ABC unites people with lupus and key stakeholders from government, industry and academia into a single collaborative entity to overcome scientific hurdles in lupus drug development that are beyond the capacity of any single organization.

Current Lupus ABC members include representatives from the lupus patient community, including patient-focused non-profit organizations, academia, industry, FDA (CDER and CBER), NIH (NIAID, NIAMS), and professional societies (ACR and CARRA). Convened and managed by Lupus Research Alliance, Lupus ABC is governed by the Research Committee (RC) and the Lupus Voices Council (LVC). The RC, comprised of representatives from industry, academic, medical, and patient communities, as well as governmental agencies including the FDA, sets priorities for the consortium and defines projects that address these priorities. The LVC, comprised of individuals living with lupus, their family members or care partners and representatives of advocacy organizations, ensures that the perspectives of individuals with lupus are incorporated into the work of Lupus ABC. Lupus ABC membership is open to patient organizations, companies, federal agencies, and other entities committed to active and consistent participation in the PPP's work to advance the development of new treatments and

cures for lupus. Additional information about this consortium can be found at www.lupusabc.org.

PROGRAM DESCRIPTION

This Request for Proposals (RFP) seeks applications for projects aimed at addressing the most critical barriers to the development of lupus treatments in the pre-competitive setting. Projects supported by Lupus ABC are executed through Lupus ABC Working Groups (WGs), under the strategic direction of the Lupus ABC RC and LVC. Individuals whose proposals are selected will be invited to co-lead the relevant WG. Lupus ABC WGs have specific objectives and milestones and typically meet monthly, and more frequently as needed. End products are reviewed and endorsed by the Lupus ABC RC with input from the LVC.

Lupus ABC seeks projects that would uniquely benefit from the support of a collaborative, public-private partnership with regulatory science involvement and that are too complex for any single organization or group to accomplish.

Projects should help address challenges in lupus drug development that have the highest potential for improving the health outcomes of individuals with lupus.

Examples of project focus areas may include, **but are not limited to**:

- Novel clinical trial designs (e.g., platform trials, adaptive designs, master protocols, digital tools, and virtual assessments)
- Overcoming barriers to trial participation (e.g., eligibility criteria, assessments)
- Novel and organ-specific endpoints (e.g., NPSLE, cognitive impairment, musculoskeletal involvement)
- Predictive biomarker development/companion diagnostics
- Data standardization in lupus clinical settings

Examples of project deliverables may include, **but are not limited to**:

- Scientific forums on critical challenges in the development of therapeutics for lupus, aimed at producing actionable strategies
- Roadmaps or consensus-based recommendations
- Development/validation of novel assessments or endpoints
- Biomarker qualification plans
- Position papers

Projects currently supported by Lupus ABC include:

Treatment Response Measure for SLE (TRM-SLE)

Led by Eric Morand, M.D., Ph.D. (Monash University), this project aims to develop new outcome assessments designed specifically to measure treatment effects in clinical trials that are meaningful to patients and clinicians. Current SLE trial assessments have limitations, including that they are adapted from pre-existing disease activity measures (not fit-for-purpose for measuring treatment response), may lack sensitivity to change, may lack a strong evidence base for thresholds/weighting, have limited validation, and

often rely on complex and obscure endpoints. The group undertook a multi-step process to address these limitations, starting with a literature review to define the unmet need and approach. The group recently completed a two-stage modified Delphi process to identify which domains to prioritize within the measurement and published the results of this effort in *Lupus Science and Medicine* in March 2025. The final stages of TRM-SLE development will address domain measures and response definitions, as well as integrate the domains into a finalized measurement instrument.

Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI)

Established in January 2024 and led by Benjamin Chong, M.D. (University of Texas Southwestern Medical Center), this Working Group aimed to refine CLASI to align with FDA standards for use as an outcome measure for cutaneous lupus in clinical trials. With an unprecedented opportunity to have an open dialogue with the FDA on its concerns with the use of CLASI, the Working Group compiled published and unpublished data to address these concerns. The CLASI WG is currently focused on determining the threshold of CLASI activity improvement that is deemed clinically meaningful in trials and defining the minimum CLASI activity score needed for inclusion.

Immune Reset Working Group

This working group was originally launched in March 2024 as the Chimeric Antigen Receptor (CAR) T cell therapy WG (led by Elena Hsieh, M.D., and James Chung, M.D., Ph.D.). The WG aimed to address outstanding questions on the use of CAR T cell therapy in lupus, integrating perspectives from key stakeholders, including the FDA's Center for Biologics Evaluation and Research (CBER), into a position paper on the key considerations to advance CAR T cell therapies for lupus (under review). The next phase of the working group (led by Barbara Mittleman, M.D., and Maximilian König, M.D.) will expand the scope beyond CAR T cell therapy to all immune cell-engaging therapies with the potential to achieve durable treatment-free remission in lupus, and project plans are under development.

Patient Reported Outcomes (PRO) for Lupus Working Groups

Lupus ABC convened an in-person meeting in October 2024 to determine the current state of lupus PROs and identify the potential focus of a Lupus ABC working group on this topic. Based on the input from this meeting, two PRO-focused WGs were launched recently. One, led by Zahi Touma, M.D., Ph.D. (University of Toronto), will focus on identifying domains of SLE important to patients and selecting outcome measures best suited to capture these domains. A second effort, chaired by Patti Katz, Ph.D. (UCSF), will focus on harnessing existing PRO measurement data from lupus clinical trials to examine the performance of PRO measures in trial settings and to develop recommendations for their use in lupus clinical trials.

FUNDING CONSIDERATIONS

Lupus ABC is not a traditional funding body. Instead, the unique benefit of being a Lupus ABC-supported project is the opportunity to engage in a meaningful collaboration

and real-time discussions with key stakeholders, including representatives from academia, industry, government, and the patient community (Disclaimer: FDA staff involvement is limited to providing a general perspective on regulatory standards, scientific issues, and scientific gaps related to precompetitive development. Involvement is not related to any specific regulatory application, product, or other non-public information). Lupus ABC provides dedicated administrative and project management support to facilitate the activities of each WG, including covering expenses related to organizing key meetings and defraying publication costs. Please note that this Request for Proposals does not include project-specific funding. However, we request that applicants submit a detailed project budget, including current funding sources and any potential alternative sources to enable the Review Committee to assess the feasibility of the proposed work.

In exceptional cases, and only with a compelling justification, limited project funding may be provided by Lupus ABC. Justifications must clearly explain why no other funding sources are available to support the proposed activities. In these circumstances, Lupus ABC is also open to exploring alternative or supplemental funding models or sources to support the project. All applicants are strongly encouraged to seek additional extramural support.

- Project Duration: One to two years, with potential for competitive renewal for projects with demonstrated substantial progress

ELIGIBILITY

This RFP is open to researchers from academic institutions, industry, non-profit research institutes, and government agencies worldwide.

APPLICATION PROCESS AND INSTRUCTIONS

A two-stage application process will be employed. A Letter of Intent (LOI) will be used to judge criteria listed below under “proposal evaluation criteria.” Applicants whose LOIs successfully pass this first review stage will be invited to submit a full application. Applicants are encouraged to consult with Lupus ABC staff to discuss the responsiveness of their proposal to this program.

LOIs should be submitted electronically via the [LRA Grants Management System](#) by **11:59pm US ET on the stated deadline.** Applicants whose LOIs are selected for further consideration will be invited to submit a full proposal.

All templates and instructions, including the Request for Proposals and the Letter of Intent template, can be downloaded from within the LOI form. **Please note that when a template is provided, it must be used.**


The following information is required to submit a complete LOI:

Applicant

- The Institution Information and Contact Information will be preloaded with information from the organization profile and applicant profile, respectively.
- For Role, select “Applicant/PI” from the dropdown menu.
- Select from the dropdown menu how the applicant learned about this opportunity.
- Upload, as a PDF, a standard [NIH Biosketch](#) for the applicant. Applicants who are not based in the United States may submit a copy of their curriculum vitae, which must be limited to five pages in length.
- Upload, as a PDF, an [Other Support Page](#) for the applicant. This should detail all other financial support (current as of the date of the submission) available to the applicant for their research endeavors.

Give Other Users Access to Proposal

To provide institutional administrators and research/grants administrators with access to the LOI form:

1. Click the Collaborators icon .
2. Enter the required information.
3. Clicking on the plus sign button will add additional rows.
4. Click the Save button at any time to save your work.
5. Click the Invite button. An email with the subject line “Invitation to Collaborate on LRA Grant Proposal” will be sent inviting them to work on the grant proposal. They will be asked to click a link to accept or decline the invitation. Users who accept but are not yet registered in the system will need to do so.

*NOTE: A user added as research/grants administrator will be able to edit the LOI form but will not be able to submit it. Only the applicant and any users added as institutional administrators will be able to both edit and submit the LOI form. **PLEASE NOTE: Only one user can edit the LOI form at a time.***

Project Information

- Enter the title of the proposed project.
- Keywords: Select all that apply.

Attachments

Cover Page: Provide the name, institution, position, and role on the team for each Co-PI/key team member on the cover page template provided on the LRA Grants Management System. Upload as a PDF.

Letter of Intent: Upload the **Letter of Intent** as a PDF. The Letter of Intent template provided on the LRA Grants Management System must be used. Margins must not be less than .5 inches on each side and 12-point Times New Roman or the equivalent should be used for the text. The LOI, responsive to the specific instructions above, **should not exceed two pages**, including any figures, tables, and legends. References are not included in the page limit. The information listed above must be included in the indicated order.

1. A description of the project and how it would advance Lupus ABC's objectives, including:
 - a. Brief Background
 - b. Impact on advancing lupus therapies or therapeutic innovation
 - c. Approach and key deliverables
 - d. Description of how the project will uniquely benefit from participation of all Lupus ABC stakeholder groups (patients, industry, academic, government, regulatory, etc.).
 - e. Description of engagement of people living with lupus and/or their care partners throughout the project
2. A brief 1 or 2-year timeline and milestones for the proposed activities
3. A proposed total budget and current or anticipated sources of funding, if any, including any request from Lupus ABC along with justifications
4. References (not included in page limit)

Electronic Signatures

When the applicant is ready to submit the LOI:

1. Click on the checkbox next to, "By signing, the applicant certifies that the information contained in the LOI is true, complete, and accurate to the best of their knowledge."
2. Enter the applicant's name in the LOI Signature Box.
3. Click on the LOI Signature Date box and click the Now button. This will automatically insert the current date and time.
4. Click the Submit button to submit the LOI, then the Yes button to confirm.

LOI Restrictions

Only one LOI will be accepted per Principal Investigator (primary PI).

FULL APPLICATION

Full applications may be submitted only by applicants whose LOIs have been approved to advance to the next stage of the review process. Applications must be submitted via the LRA Grants Management System **by 11:59pm US ET on the stated deadline**. Detailed instructions for the application form will be available in the LRA Grants Management System. The application form will only be accessible to applicants with approved LOIs. **Applicants will be required to present their project to the Lupus ABC RC and LVC via zoom in April 2026 and should make themselves available for these important considerations.**

PROPOSAL EVALUATION CRITERIA:

Proposed projects will be evaluated by the Lupus ABC Review Committee based on the following criteria:

1. **Alignment** with Lupus ABC objectives:

- Overcoming obstacles to lupus drug development where regulatory input is essential
 - Ensuring that patients' experiences, perspectives, needs, and priorities are captured and meaningfully incorporated into the evaluation of new therapies for lupus
 - Enabling and/or accelerating an open, collaborative and community-wide approach to addressing challenges in lupus drug development
 - The extent to which the public-private partnership (PPP) model of Lupus ABC is necessary for the success of the project. More information on PPPs can be found at: <https://www.fda.gov/drugs/science-and-research-drugs/scientific-public-private-partnerships-and-consortia>
2. **Impact** on advancing lupus therapies and improving therapeutic innovation
 3. **Feasibility** of the project as a Lupus ABC WG, including clear approach and deliverables
 4. **Engagement** of people living with lupus and/or their care partners throughout the project

AWARD TERMS AND CONDITIONS:

All supported projects must adhere to the following terms and conditions:

1. Active engagement of people living with lupus in project activities.
2. Quarterly reporting of project progress to the Lupus ABC Research Committee.
3. Acknowledgement of Lupus ABC support in any publications or presentations related to this project.
4. Strict adherence to the guidance set forth by the FDA's [Center for Drug Evaluation and Research Manual of Policies and Procedures](#) as it relates to Public Private Partnerships (PPPs).

KEY DATES

- **RFP Release Date:** August 15, 2025
- **Letters of Intent Deadline:** October 3, 2025
- **Letter of Intent Decision:** November 12, 2025
- **Full Proposal Deadline*:** January 16, 2026
- **Presentation to Committees:** April 14 and 15, 2026
- **Full Proposal Decision:** April 30, 2026

*By invitation only

INQUIRIES

LupusABC@lupusresearch.org

LRA Grants Management System:

For assistance with the electronic grant application process, please contact the Lupus ABC team at lupusabc@lupusresearch.org.