



Request for Proposals for the Analysis of Lupus Patient-Focused Drug Development Initiative Pre-Meeting Survey Data

Release Date: October 19, 2018

Letter of Intent Required: December 14, 2018

Application Due Date: January 31, 2019

Notification Date: March-April 2019

Anticipated Start Date: June 3, 2019

Period of Performance: Six (6) months

Anticipated Number of Awards: Up to 2 awards for \$25,000 each

Background

The Lupus and Allied Diseases Association, the Lupus Foundation of America, and the Lupus Research Alliance collaborated on an Externally-led Patient-Focused Drug Development (PFDD) Initiative culminating in a meeting in September 2017 and a [report](#), *Lupus: Patient Voices*, that was released in March 2018. A high-level data analysis was conducted for the purpose of the *Lupus: Patient Voices* Report. ***This RFP is soliciting proposals for a more detailed data analysis that will further the understanding of the perspectives of people with lupus in a way that will help the lupus research community gain insight from the patient data and viewpoint in order to help inform future research, and clinical and regulatory strategies.***

The *Lupus: Patient Voices* Report reflects the three organizations' account of the unique perspectives of people with lupus and their representatives who participated in the public meeting, responded to the pre-meeting survey, and/or submitted post-meeting comments.

The Lupus PFDD Meeting was designed primarily to provide individuals with lupus and their representatives an opportunity to share their unique experiences to help the FDA and the biopharmaceutical industry to:

- Understand the lupus patient journey and recognize patient preferences and risk tolerance so these may be translated into improved clinical trial designs and selection and/or development of measurable outcomes relevant in lupus drug development. In addition, this information could be incorporated into the benefit-risk framework being used in regulatory decision making;
- Demonstrate the complexity and heterogeneity of lupus, with the end goal of development programs and trial designs that will reflect these aspects of the disease;

- Create a practical, scientifically rigorous framework that incorporates patient preferences and patient reported outcomes into lupus clinical research and trials to ensure that trials are measuring not only statistical success but also demonstrating meaningful benefit to the individual with lupus; and
- Ensure that people with lupus understand the value of their participation in the drug development and clinical trials process by acknowledging how their contributions impact decision-making and outcomes at all levels to both improve their own health-related quality of life as well as the quality of life for the next generation of people with lupus.

Prior to the Lupus PFDD Meeting, more than 2,100 people completed a 46-question survey about their experiences with lupus. The data from these surveys were used to shape the meeting, and similar questions were posed and additional data were collected in the form of polling questions during the meeting via a web-based data collection tool.

Persons with lupus and their representatives (defined as parents or legal guardians of children with lupus) were invited to respond to the survey that was designed to yield better understanding of the experience of living with lupus. The survey was based on similar polling questions used at FDA-led PFDD meetings and expanded to capture additional detail about disease symptoms, impacts on daily life, and experiences with treatments. The survey was designed by the three organizing groups with input from lupus experts, including clinicians. The survey was available for over two months on a dedicated website and in paper form, and both formats were available in English and Spanish. The survey was distributed through a variety of channels including lupus community networks, websites, social media, and e-mail blasts and as well as hard copies distributed at events, support groups, and a camp for children with lupus. Complete responses were received from 2,119 individuals in the U.S., of whom 98% were individuals with lupus and 2% were parents or representatives of children with lupus. Responses were received from people across the U.S. and over 100 people with lupus who live in other countries, although the data from international respondents were not included in the analysis for the final report.

The *Lupus: Patient Voices* Report and the survey questions which are included in the report's appendix, can be found at www.LupusPFDD.org.

The Lupus and Allied Diseases Association and the Lupus Research Alliance will fund up to two grants to carry out an in-depth analysis of the pre-meeting questionnaire data, a maximum of \$25,000 per award for a six-month period of performance.

Project Goals

Since the *Lupus: Patient Voices* Report is a high-level analysis of the data, this RFP seeks to enable a more detailed examination that stratifies it by various elements and has the potential to yield insights to benefit lupus research and development and the drug review process.

In keeping with the original intent of the PFDD initiative, any data and insights derived from additional analysis are expected to be shared such that the results are publicly available to benefit all who may be interested.

The cleaned and deidentified data set will be shared as an Excel file. It includes responses from 2,119 persons with lupus or their representatives who live in the U.S. An overview of the data collection

process can be found in the *Lupus: Patient Voices* Report in the section titled “Meeting design and data collection” summarized above.

Eligibility

Individuals with a relevant masters or doctoral degree (MD, PhD, DO or equivalent), holding a faculty, or equivalent, position at the Instructor level and above at an academic or research institution in the United States or Canada are eligible to apply. Applicants must have an established track record in biostatistics and/or relevant areas.

Employees of biopharmaceutical companies are not eligible to apply. Companies interested in obtaining the data for further analysis should contact:

Kathleen A. Arntsen

President & CEO

Lupus and Allied Diseases Association, Inc.

315-264-9101

Kathleen@LADAinc.org

LOI Guidelines

A Letter of Intent (LOI) is required and must be submitted electronically, via [proposalCENTRAL](#), by 5pm EST on December 14, 2018. The LOI should not exceed 2 pages. Figures, tables and legends are included within the page limit. However, citations are not counted towards the page limit. Full applications may be submitted only by applicants whose LOI has been approved and who have been invited to advance to the next stage of the process.

Application Guidelines

Applications must be submitted electronically, via [proposalCENTRAL](#) by 5pm EST on January 31, 2019 and should contain the below information (please log into [proposalCENTRAL](#) for detailed description). Paper applications are not accepted.

1. *Abstract*: Summary of the proposed data analysis plan and how it will use statistical methods to investigate the data set in order to advance the understanding of patient perspectives to aid in the development of new treatments for lupus. This must be written in lay language geared to a twelfth-grade reading level and suitable for use in publications (not to exceed 3,000 characters).
2. *Data Analysis Plan*: The data analysis plan should not exceed five pages and should include the following information: the types of analyses that will be undertaken using the data set; highlight their significance; describe the statistical approach(es) that will be used, the anticipated outcomes and alternative strategies; explain how the data will be stored to ensure confidentiality; provide a data sharing plan and a publication strategy; describe the relevance of the approach to the goals stated above.
3. *Biosketch*: A curriculum vitae (CV) or standard NIH Biosketch for all key personnel working on the project.
4. *Detailed Budget and Summary*: A budget for the project prepared in U.S. dollars. The budget should be for six months and should not exceed \$25,000 total or include indirect costs.
5. *Budget Justification*: A detailed justification for the budgetary requests must be provided and should include the following line items: personnel and supplies. Funds must not be used to pay

for tuition or education expenses or to purchase equipment. Submission should not exceed 2,000 characters.

6. *Facilities & Equipment Description*: A short description of the facilities and equipment available to support the project.
7. *Consultant/Co-Investigator/Collaborator Letters*: Optional, submit only if relevant to the application.
8. *Signed Cover Page*: The signed cover page should be uploaded electronically and reflect the applicant's agreement to abide by the rules governing grant awards from the Lupus and Allied Diseases Association and Lupus Research Alliance. Instructions are available on the [proposalCENTRAL](#) website.

Review Criteria

A review group will consider each of the following criteria in assigning the application's overall score, weighting them as appropriate for each application.

- **Relevance** to the PFDD program goals and demonstrates an understanding of the PFDD and the type of information necessary to aid in bringing forth the patient perspective and disease characteristics from the patient viewpoint in a way that will benefit lupus research and drug development
- **Feasibility** to accomplish the proposed work within a six-month time frame
- **Significance** of the project as indicated by the types of analyses proposed
- **Approach**: Are the analyses adequately developed and appropriate to the goals of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Does the publication plan address the program goals?
- **Investigator**: Is the investigator appropriately trained and well-suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?
- **Environment**: Does the environment in which the work will be done contribute to the probability of success? Does the proposed data analysis plan employ useful collaborative arrangements? Is there evidence of institutional support?

Terms of Award

Grants will be supported for up to \$25,000 for a period of up to six months. Awards will not cover indirect costs. It is anticipated that two grants will be awarded.

The Lupus and Allied Diseases Association and the Lupus Research Alliance are committed to the publication and dissemination of all information developed under this award mechanism. Recipients must agree to this principle and must take steps to facilitate data sharing following publication/presentation of the analysis.

Awardees will receive the deidentified data in an Excel spreadsheet and must guarantee secure storage of the data file and any analyses developed from it.

Grantees acknowledge that the original data is owned by the conveners of the Lupus PFDD meeting and cannot under any circumstances: publish without permission and acknowledgement, share data with any third party not named in the original application, publish data in any way that can lead to the identification of individuals who took the survey; cannot use the dataset for any reason beyond the scope of this project.

Data Ownership, Acknowledgement, and Publications

The Lupus and Allied Diseases Association, Lupus Foundation of America, and Lupus Research Alliance own the Lupus Patient-Focused Drug Development pre-meeting survey data. The Lupus Foundation of America has agreed that Lupus and Allied Diseases Association and Lupus Research Alliance can share the data for further analysis and interrogation through this RFP. All three organizations must be acknowledged in any publications that result from the work done through the award of this RFP using a statement to be provided upon grant award.

A goal of this RFP is for the results of any analyses of this data set to result in publications. The survey was conducted as a means to publicly share lupus patient perspectives to help advance drug development through incorporating the patient viewpoint. The award recipient must agree to make a good faith effort to publish their findings, so they are accessible to all interested parties. A condition of grant award will include agreeing to these terms.

Relevance to the Mission of the Lupus and Allied Diseases Association and the Lupus Research Alliance

The Lupus and Allied Diseases Association, Inc., was founded in 1978 and is a national patient advocacy organization dedicated to enhancing quality of life by educating and empowering individuals impacted by lupus and allied diseases and other conditions of unmet need. As a passion-driven charity led by individuals with lupus and their loved ones, we strive to ensure that the patient perspective is included and recognized as an equal voice in healthcare, public policy and across the research continuum. It is our goal to improve access to care and quality of life by fostering collaboration among stakeholders and promoting innovative advocacy, education, awareness and biomedical research initiatives that will identify causes, advance better diagnostics, and discover superior treatments and cures.

The Lupus Research Alliance is the world's leading private funder of lupus research. Established in 2016 – from the merger of the Alliance for Lupus Research, the Lupus Research Institute, and the S.L.E. Foundation – the Lupus Research Alliance was created to improve treatments for lupus while advancing toward a cure. This effort includes raising funds and advocating on behalf of the lupus community. We believe that scientific research is the most powerful way we can improve the lives of people living with lupus, today and over the long term. By pushing the limits of scientific exploration and shepherding new discoveries into potential treatments, we aim to seize every opportunity that will help ease the burden of people living with this difficult disease.

Key Dates

RFP Release:	October 19, 2018
LOI:	December 14, 2018
Earliest Submission:	December 21, 2018
Application Due:	January 31, 2019

Reviews: February-March 2019
Response to Applicants: March-April 2019
Earliest Anticipated Start: June 3, 2019

Inquiries

Diane Gross
National Director of Advocacy and Programs
Lupus Research Alliance
646-884-6000
dgross@lupusresearch.org

proposalCENTRAL:

For help with the electronic grant application process, please contact the help desk of proposalCENTRAL
pcsupport@altum.com
+1-800-875-2562, extension 227