

Diversity in Lupus Clinical Trials – FDA-Requested Listening Session (Session #2)

April 2, 2021

Objectives of Session

- To gain a better understanding of Lupus patients and caregivers perspectives on:
 - Knowledge, attitudes, and beliefs about Lupus clinical trials and participation in the trials.
 - Preferred sources when looking for information about Lupus.
 - Lupus disease burden.
 - Concepts that may be used in a Lupus clinical trial diversity campaign developed for the FDA.

This information will be used to better understand lupus clinical trial participation perspectives as well as inform the development of a national outreach and multi-media campaign to promote increased racial and ethnic minority participation in lupus clinical trials.

Discussions in FDA Listening Sessions are informal and not meant to replace, but rather complement existing patient engagement opportunities in the Agency. All opinions, recommendations, and proposals are unofficial and nonbinding on FDA and all other participants. This report summarizes the input provided by patients and those representing patients with Lupus at the meeting. To the extent possible, the terms used in this summary to describe specific manifestations of Lupus, and the health effects and impacts, reflect those of the participants. This report is not meant to be representative of the views and experiences of the entire Lupus patient population or any specific group of individuals or entities. There may be experiences that are not mentioned in this report.

Summary of Discussion by Question

1. Could you describe how you might get involved in participating in a clinical trial?

- Over half of the participants shared that they would obtain information about clinical trials through the Lupus Foundation of America. One participant added that they would obtain information regarding clinical trials through their local Lupus foundation.
- Two participants mentioned they would look to the Lupus Research Alliance for information about Lupus clinical trials.
- Two participants stated they would speak directly to their rheumatologists about Lupus clinical trials and whether they would be a good candidate to participate.

2. What do you think are the pros and cons of participating in a clinical trial?

- Over half of the participants shared that a pro of their or their children's participation in clinical trials would be the positive outcomes clinical trials could have on the Lupus community. A patient with Lupus mentioned specifically the pro of advancing Lupus treatments for the community.
- One participant mentioned the pro of access to new and investigational treatments as a result of their child's participation in a clinical trial.
- A majority of the participants on the call mentioned the fear of the unknown of clinical trials as a con. One participant expressed their concerns about feeling like a "guinea pig" by

participating in a clinical trial. A caregiver mentioned the unknown of how a clinical trial may affect their child as a con from their perspective as well.

- Two participants mentioned the history of clinical trials and medicine in America as it relates to minority communities has caused fear and mistrust and is a con of participation in clinical trials. One caregiver relayed their child's concern about knowing the history of clinical trials within the African American community and how that has impacted their stance on participating.
- Another con shared by two participants is the concern of potential long-term impacts and side-effects of participating in a Lupus clinical trial.

3. *What would convince you to be a part of a Lupus clinical trial?*

- A majority of the caregivers on the call mentioned being unable to answer this question on behalf of their children.
- One caregiver shared that if they were making the decision whether their child would participate in a Lupus clinical trial, they would reach out to patients with Lupus who had participated in clinical trials already for their advice and input.
- Three of the participants - two caregivers and one patient - stated that there probably is nothing that could convince their children or themselves to participate in a clinical trial. A caregiver shared that their child has already been through so much. A Lupus patient agreed that they too feel as though they have already dealt with too much. Another participant noted that their child's knowledge of the history of clinical trials in minority communities as the primary reason why they would not participate in a clinical trial.
- One caregiver indicated that they would feel more comfortable with their child's participation in a Lupus clinical trial if they received more information about the trial.
- One caregiver said that they would consider participating in a Lupus clinical trial if they were compensated substantially.

4. *Do you think people in racial and ethnic minority groups face barriers or obstacles to participating in clinical trials?*

- The answer to this question was a unanimous yes.

4a. *If yes - What do you think could be done to overcome these obstacles/barriers that might ensure more diverse representation in Lupus clinical trials?*

- All the participants shared that educating minority communities on Lupus clinical trials would go a long way to overcoming obstacles/barriers minority Lupus patients face. One participant stated that schools and employers can help in educating people within communities on Lupus clinical trials, which would help increase diversity.
- Lack of resources was another obstacle mentioned by the majority of participants. It could be the lack of reliable transportation, so providing transportation could mitigate that. Two participants mentioned providing affordable healthcare to the community. One participant indicated providing resources to the community as a whole.

- One caregiver believed that transparency among the people organizing the Lupus clinical trial, including the scientists and physicians, is important to overcome obstacles and barriers.
- A Lupus patient suggested increasing diversity among those conducting the clinical trial, including members of the medical community, would help encourage participants of diverse backgrounds to take part in Lupus clinical trials.

5. Review the campaign titles and taglines below and answer the following questions:

- **#1 - Join the Fight:** *Join the fight and increase diversity in Lupus research.*
- **#2- Count Me In:** *Make sure diverse participants like you are counted in Lupus research.*
- **#3 -Take Charge:** *Take charge and make Lupus research more diverse.*

5a. Out of the 3 titles, which do you like the most? Which is your least favorite? Why?

- Four participants liked #3, “Take Charge,” the most. Two participants shared that “Take Charge” felt empowering and made them feel like the patient is part of their treatment. Another two participants liked #3 because it gave them the sense that the campaign is more inclusive than just the patient. It also speaks to the caregiver, the friend, and family’s perspective.
- One participant indicated that they did not have a favorite as they believe that the Lupus community as a whole should be involved in any campaign.
- Two of the participants liked #1 the least. One participant shared that they were not fond of the word “fight” in the first campaign title and tagline. The other participant felt it was boring.
- Three participants stated that they did not have a least favorite. One caregiver shared that #1 (Join the Fight) and #2 (Count Me In) are okay, they just feel unoriginal.

5b. If you could make one change to each one of these titles, what would it be?

- Two participants had similar recommendations on changes to each title. They believed #1 should be changed to “Join the fight and increase diversity in Lupus research *to make a difference.*” They suggested #2 should read “Make sure diverse participants like you *and me* are counted in Lupus research.” For #3, they recommended “Take charge and make Lupus research more diverse for *all of us.*”
- One participant stated that they would add the word “everyone” to #3.
- Two participants did not offer any suggestions or changes to the titles and taglines.

6. If FDA was interested in promoting a campaign on Lupus clinical trials, where would you expect to see or hear about it? Some examples might include, TV, radio, social media, billboards, posters, magazines, etc. Are there specific places, sources, locations you might prefer? For example, on social media you might say Facebook or Twitter; on TV you might say different networks.

- Each participant stated that they expected to see or hear about a campaign on Lupus clinical trials on social media. One participant noted social media’s ability to reach audiences of all ages. Two participants highlighted Facebook and Twitter as the expected social media outlets. A caregiver also suggested video campaigns through Instagram, YouTube, or TikTok.

- Three participants stressed the importance of seeing or hearing about a campaign on Lupus clinical trials in their communities. Two of the three participants mentioned churches and schools/universities. One caregiver mentioned local community businesses like nail salons, barbershops, beauty shops, etc. They also suggested placing campaign information in community centers. Another caregiver recommended working with employers to share Lupus clinical trial information.
- Two caregivers mentioned television as an expected method to receive information on a Lupus clinical trial campaign. One participant noted that their local news anchor's wife has Lupus and raises awareness while on-air.
- Two participants recommended utilizing patient portals, such as databases healthcare systems use to communicate with patients, and emails lists to disseminate Lupus clinical trial information.
- One caregiver said that a campaign on Lupus clinical trials should be seen and heard everywhere including social media, television, radio, posters, billboards, magazines, etc.
- One participant stated that a campaign on Lupus clinical trials should involve outreach to public figures with connections to Lupus awareness. The caregiver suggested an individual, such as the Vice President of the United States, whose sister has Lupus.
- One participant shared that they do not believe television would be a useful outlet for a campaign on Lupus clinical trials. They believe that people have switched to streaming platforms and using their phones.

7. *In this survey, you shared a little about what it's been like to live with and manage Lupus. You talked about your biggest worries, symptoms and concerns. Is there anything else you would like FDA to know about your experience with Lupus?*

- Two participants asked for more research into and more information provided on holistic and nutritional treatment options for Lupus patients. A caregiver noted that their child complains about how many medications they must take and would appreciate alternatives.
- Two caregivers mentioned their desire for a way to expedite Lupus treatments for pediatric patients. One caregiver shared that the way Lupus impacts children is not much different than the way it affects adults, so that should help expedite bringing new medications in the market.
- One participant shared that they are fearful for their child with lupus every day. Caregivers and patients have to be courageous and that all the effort is worth it as they are saving lives.

Partner Organizations

- The Reagan-Udall Foundation for the FDA assisted with producing the summary of this meeting. The Foundation was present during the listening session.
- Office of Patient Affairs (OPA) contractor support assisted with producing the summary of this meeting.

FDA Divisions Represented

- **Office of the Commissioner**

- Office of Patient Affairs (*organizer*)
- Office of Minority Health & Health Equity (*requestor*)
- Attendees: Office of Chief Scientist, Office of Regulatory Science and Innovation; Office of Clinical Policy & Programs; Office of Combination Products; Office of Orphan Products Development
- **Center for Biologics Evaluation and Research (CBER)**
 - Attendee: Office of the Center Director
- **Center for Drug Evaluation and Research (CDER)**
 - Attendees: Office of Medical Policy, Office of Prescription Drug Promotion, Division of Advertising & Promotion Review II (DAPRII); Office of New Drugs, Office of Drug Evaluation Science, Division of Clinical Outcome Assessment (DCOA); Office of New Drugs, Office of Immunology and Inflammation, Division of Rheumatology & Transplant Medicine (DRTM); Office of New Drugs, Office of Neuroscience, Division of Psychiatry (DP); Office of New Drugs, Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine, Division of Rare Diseases and Medical Genetics (DRDMG); Office of Translational Sciences, Office of Biostatistics, Division of Biometrics I (DBI); Office of Translational Sciences, Office of Biostatistics, Division of Biometrics III (DBIII); Office of Translational Sciences, Office of Biostatistics, Division of Biometrics IV (DBIV)
- **Center for Food Safety and Applied Nutrition (CFSAN)**
 - Attendee: Office of Cosmetics and Colors

Patients and Caregivers Represented

Four caregivers and one patient participated in the listening session representing Lupus adult and pediatric patients:

- All patients and caregivers self-identified as belonging to a racial/ethnic minority group.
- All patients and caregivers expressed hesitations and concerns about participating in clinical trials. A majority of the caregivers expressed the inability to speak for their children. The patient participant noted they would most likely not participate in a clinical trial.
- The age of patients represented in the Listening Session ranged from 13-37.

Prior to the Listening Session, Participants Shared

- A majority of participants shared that fatigue was the biggest burden living with Lupus.
- One caregiver noted that their biggest burden is the inability to take away their child's pain and the unknown of tomorrow for their child.

Financial Interest

Participants did not identify financial interests relevant to this meeting and are not receiving compensation for participation in this listening session.