

Diversity in Lupus Clinical Trials: FDA-Requested Patient Listening Session (Session #1)

March 31, 2021

Objectives of Session

- To gain a better understanding of Lupus patients' 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 clinical trial participation perspectives as well 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?*

- All of the participants indicated that they would consider or get involved in a clinical trial if their rheumatologist recommended it and thought that they were a good fit for the clinical trial.
- Over half of the participants shared that they would obtain information about clinical trials through the Lupus community including Lupus support groups and advocacy groups. One participant added that people who had/were participating in clinical trials themselves are a source of information.
- One participant mentioned trying to find information from websites, such as clinicaltrials.gov and Lupustrials.gov.
- One participant stated they learn about clinical trials through social media.

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

- A majority of the participants indicated that the pros of participating in a clinical trial are obtaining a potential treatment that is potentially more effective or has fewer side-effects ahead of its availability in the market and the possibility of helping themselves and others in the Lupus community.
- Other pros shared by two participants were potentially reducing the number of medications and having the support and input from the medical community.

- All of the participants mentioned the possible side-effects as one of the cons of participating in a clinical trial. A majority of the participants were worried that being in a clinical trial might necessitate reducing or stopping their current medications leading to harm. One participant had concerns about the experimental drug being ineffective, and another participant mentioned the possibility of getting the placebo.
 - Other cons shared by two participants were transportation issues and time commitment, such as missing work.
 - A participant indicated that financial burden and the effects on other family members are cons of participating in a clinical trial.
3. ***Follow-up question from the Office of Minority Health and Health Equity: If you feel comfortable, how many medications are you are currently on for your regimen?***
- The number of medications that the participants were on varied between two to seven. One participant mentioned taking Hydroxychloroquine, a pain medication, and a steroid as needed.
4. ***Follow-up question from Patient-Focused Drug Development: When you hear about trials from friends, is it through social media or some other way? If social media, what type of social media?***
- Two participants responded that they are most likely to hear about clinical trials from social media, such as Facebook, Instagram, and links shared between the Lupus communities and during meetings or conversations with others in the Lupus community.
5. ***What would convince you to be a part of a lupus clinical trial?***
- A majority of the participants indicated that having their rheumatologist on board would convince them to be a part of a Lupus clinical trial.
 - Over half of the participants would be motivated if their current medication or treatment plan was not working.
 - Two participants mentioned the time commitment needed to participate in a clinical trial and they would participate if the time commitment worked for them.
 - Some participants expressed interest in potential new treatments targeting organs/issues rather than Lupus-associated symptoms, having clinical trial personnel participate in outreach efforts, having the opportunity to help themselves and others, outweighing the pros and cons, and knowing the availability of clinical staff to answer questions.
6. ***Follow-up question from Office of Minority Health and Health Equity: Could you better describe what kind of engagement would be needed to make you feel comfortable that the research community it invested in your well-being?***
- One participant responded that they would want the research community to be involved with the community on levels other than clinical studies, such as attending support group meetings, giving presentations, answering questions, and developing trust.
7. ***Further follow-up from Office of Minority Health and Health Equity: Does racial and ethnic diversity of the researchers engaging with you on the clinical trial matter?***

- One participant responded and confirmed that the diversity of researchers matters.

8. *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.

8a. *If yes - What do you think could be done to overcome these obstacles/barriers that might ensure more diverse representation in Lupus clinical trials?*

- Almost all of the participants mentioned that the history and mistrust of clinical research was a hurdle for racial and ethnic minorities to participate in current clinical trials.
- Lack of resources was another issue mentioned by the majority of participants. It could be the lack of reliable transportation, so providing transportation could mitigate that. It could also be financial hardships, which could be overcome by financial compensation. Finally, it could be other commitments, such as childcare and providing for childcare could motivate some to participate.
- Two participants mentioned the lack of awareness and knowledge about clinical trials. Educating people about clinical trials through seminars, meetings, going into the community and answering questions, spreading knowledge about planned/ongoing clinical trials, etc. would also help enroll more minorities into clinical trials. In addition to outreach efforts, building trust from doctors with diverse backgrounds would be needed.

9. *Follow-up question from the Office of Minority Health and Health Equity: How many of you learned about clinical trials from your doctors?*

- Two participants responded that they have not been requested to participate and have not received any information about clinical trials despite having expressed interest.
- A participant referenced hearing about clinical trials from their doctor located in a big city, but did not hear about clinical trials from their doctor located in a small town.

10. *Follow-up question from the Office of Minority Health and Health Equity: In terms of people coming in and educating the community about clinical trials, do you have a preference about who should do the education? Would you prefer patients who are living with Lupus and have participated in clinical trials, or physicians, or community workers who could bridge the gap?*

- Two participants concurred that all of the above should be involved in the outreach and education. One participant specified the need for black doctors and black researchers to engage with the black community, community leaders to bridge the gap, and seminars to educate the minorities.

11. *Review the campaign titles below and answer the following questions:*

- #1 - *Join the Fight/Joining the fight*
- #2- *Count Me In*
- #3 -*Take Charge*

11a. *Out of the 3 titles, which do you like the most? Which is your least favorite? Why?*

- One participant liked #1 the best because it made them think of battling the disease. Two participants liked #2 the best because it made them think of being included and being involved in the community. Two participants liked #3 because it made them feel empowered, it had a positive feel to it, and it was a call to action.
- Four participants liked #1 the least, primarily because of the word “fight” and its association with losing a fight. Fight was also perceived as being negative, triggering, and exhausting. It was also perceived as being overused and tiresome. One participant liked #3 the least because it seemed to lack compassion. One participant was neutral about #2 and #3 because they seemed to have a good message but were not powerful enough.
- One participant indicated that none of the titles made them think of “diversity.”

11b. What do you like most and least about each of these campaign titles?

- All four participants, who did not like #1, disliked the word “fight” because it made two participants think of losing a fight, it was triggering for one participant, and one participant thought it was overused. Two participants liked the word “join” in #1 because it made them feel involved. One participant who liked #1 the most liked the word “fight” because it was indicative of battling Lupus and disliked “join” because it made them think of unwanted membership.
- For #2, one participant liked the entire title because it made them feel included. Another participant thought it was an opportunity to be involved in the community. One participant did not like the word “in” because they would rather be “out” of the situation.
- The one participant, who liked #3 the most, felt empowered by it. The participant that liked #3 the least did not want to “take charge” of the campaign, but just wanted to be involved. One participant was neutral about #3 because it had a good message, but it was not concise. One participant liked that #3 implied trying to control Lupus, but disliked that it seemed to lack compassion.

11c. If you could make one change to each one of these titles, what would it be?

- For #1, three participants preferred removing the word “fight.” Suggestions ranged from replacing it with “cause,” “movement,” or “campaign.” One participant recommended changing the title to “win the fight.”
- For #2, two participants would not change anything, and one would replace it with something that would make them move to action. One participant was neutral about #2 and did not have suggestions for change. One participant recommended changing it to “Count On Me.”
- For #3, one participant would not change anything, another participant would change the word “charge,” and one participant recommended changing it to “take the lead.”

12. Review the campaign taglines below and answer the following questions:

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

12a. Out of the 3 taglines, which do you like the most? Which is your least favorite? Why?

- The responses varied across the participants. One participant liked #1 because it indicated asking diverse participants to participate in this research and captured the struggle and

fight of the individuals with Lupus. One participant liked that #2 was direct and to the point. Two participants liked #3 the best because it is a call to action that makes them feel empowered.

- Two participants liked #1 the least because the word “fight” was triggering. One participant each liked #2 and #3 the least because #2 did not stand out and in #3, there seemed to be no connection between “take charge” and “diverse.” One participant would prefer replacing the “diverse” with “use your voice” or “use your power.”
- One participant was neutral about #3. Another participant liked #3 the least because it lacked compassion.
- One participant did not like any of the three taglines. They thought “fight” in #1 was a turnoff, #2 made them think like the ownership of diverse participation was on them, and they did not want to take charge as per #3.

12b. What do you like most and least about each of these campaign taglines?

- For #1, one participant did not like “join the fight,” while two liked the “increase diversity” part. Two participants liked “join,” since it is like a call for action and it made them think of being together as one. They both did not like “fight” and one did not like the blanket diversity statement either. One liked “increase diversity,” but did not like “research.”
- One participant liked everything about #2. Two participants liked the part about getting counted in Lupus research but disliked “make sure,” and one did not like the blanket diverse statement. Another participant was neutral about #2, but preferred changing “counted” to “count me in.” One participant liked “diverse participants” but did not like “counted.”
- For #3, one participant liked the “research more diverse” part, but did not like “take charge” because it felt like someone was yelling at them. Another participant did not connect to “take charge,” but connected with “make Lupus research more diverse.” Yet, another participant did not like “take charge” but liked “more diverse.” One participant liked “take charge,” since it seemed like a call to action. One participant would not make any changes.

12c. If you could make one change to each one of these taglines, what would it be?

- For #1, two participants would change “fight” to “cause.” One participant would like to change it to something positive. Another participant would change “join the fight” to “win the fight.” One participant would like to make “diverse” narrower and replace it with “racial and ethnic minorities.”
- For #2, two participants would change “make sure.” One participant would like to change the “diversity” to “minority groups like you.” Another participant would like to add “count me in” and “diverse participants.” One participant would change “counted” to “counting on you.”
- For #3, two participants would change “take charge” to “take the lead.” One participant would modify it to “take charge and make Lupus research more racially and ethnically

diverse” to specify diversity, and another participant would change “diverse” to “diversity and inclusion.”

13. 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.

- A majority of participants indicated advocacy group websites and email lists (more chances of seeing), and social media as their preferred sources. Under social media, Twitter, Instagram (better targeted ads), and YouTube (cannot skip commercials) were preferred. Although one participant preferred regular TV ads, specifically on news channels like CNN and MSNBC, another participant was against it, since they thought that most people do not pay attention to television ads. Hulu was preferred by one participant, since one cannot skip commercials on it. One participant mentioned that Facebook ads may be skipped or ignored, unless they came from the Facebook page of a church. Radio, billboards, doctor’s office, and church were suggested as other sources by the participants.

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 Orphan Products Development; Oncology Center of Excellence
- **Center for Biologics Evaluation and Research (CBER)**
 - Attendee: Office of the Center Director
- **Center for Devices and Radiological Health (CDRH)**
 - Attendee: Office of Strategic Partnerships and Technology Innovation, Division of All Hazards Response, Science and Strategic Partnerships
- **Center for Drug Evaluation and Research (CDER)**
 - Attendees: Office of the Center Director, Patient Focused Drug Development Staff (PFDD); 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

Patients and Caregivers Represented

Five patients participated in the listening session representing Lupus adult patients:

- All patients were from racial/ethnic minority groups and five of them self-identified as Black or African.
- A majority of patients expressed an interest in participating in clinical trials but have not participated in a clinical trial before.
- Patient ages ranged from 35 years old to 44 years old and they were diagnosed between 4 and 23 years back.

Prior to the Listening Session, Patients Shared

- A majority of the participants mentioned the unpredictability of the symptoms as a major burden, which hampers their quality of life and makes maintaining relationships difficult. Many mentioned the financial problems and the chronic inflammation pain as two major burdens of living with Lupus.
- A majority of the participants worry that Lupus will affect other organs leading to additional complications.

Financial Interest

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