Diversity in Lupus Clinical Trials—FDA-Requested Patient Listening Session (Session #3)

April 6, 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 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 indicated that the Lupus Foundation of America is the main source of obtaining information about Lupus clinical trials and getting involved in them.

- Three participants indicated that they would consult with their rheumatologist first, and they would get involved in a clinical trial if their doctor recommended it. One participant noted that they would talk to Lupus survivors to understand clinical trials are out there and whether it is worth the risk of exploring.

- Two participants mentioned social media as a place to get information on clinical trials.

- Getting information from websites, such as clinicaltrials.gov, John Hopkins University, and other major university websites were mentioned as other sources by the participants.

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

- A majority of the participants indicated that contributing to finding new treatments and medications to help themselves and others in the Lupus community is the top pro of participating in a clinical trial. One participant noted that participating in a clinical trial for a Lupus investigational medical product could inspire other Lupus patients to participate in Lupus clinical trials.

- Two participants noted that getting care beyond their rheumatologist and getting more frequent monitoring and support from the medical community is a major pro to participating in clinical trials. One participant indicated that finding out about additional patient/educational resources by working with the clinical trial team is a pro.

- Learning new and different things about the process of clinical trials and the education involved in participating in a clinical trial were the other pros indicated by three participants.
- Most of the participants indicated that possible risks with trying new treatments is the main con of participating in a clinical trial. Reasons included "treatment is out of balance," the treatment resulting in the body "going out of whack," possible side effects, and health risks related to changing current medications.
- Transportation issues and time commitment were the other two cons mentioned by two participants. One of the participants noted that participating in a clinical trial can interfere with their day-to-day life.
- Two participants indicated that the potential costs associated with the clinical trial, which may not be covered by insurance, and the costs for the new drugs were cons of participating in a clinical trial.

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

- Two participants indicated that their decision to participate in a clinical trial would depend on how their organs may be impacted in the clinical trial and comparing the expected outcomes from the clinical trial verses their current treatment options.
- Three participants indicated that being educated about clinical trials is key to convincing them to be a part of a clinical trial. Two of the participants noted that knowing and trusting a person who has already participated in a trial would make them feel more comfortable about participating. One of the participants mentioned that having their rheumatologist recommend the treatment would convince them to participate in a Lupus clinical trial. Another participant indicated that there is a need for more exposure to options regarding clinical trials.
- One participant would be motivated to join a trial if there was an emergency backup plan in place if things were to go wrong, and if any costs related to clinical trial participation were covered by the study. The participant indicated that they have some other medical conditions so a drug that focuses on how Lupus affects the kidneys would have their attention. Also, the participant would want to know if they can continue their other medications or would there be other alternatives while participating in the clinical trial.
- Therapies specifically targeting organs/issues, time commitment, and an opportunity to help themselves and others were some of the other reasons provided by three participants as to why they would participate in a clinical trial.

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

- A majority of the participants indicated that fear and trust issues because of historical treatment of minority groups like African-Americans, and lack of awareness and knowledge about clinical trials, were two major barriers in participating in clinical trials.
- Educating people about available studies; benefits; effects of clinical trials through testimonial meetings with Lupus survivors, who are trusted by people and have participated in a clinical trial before; outreach efforts; talking to communities such as churches that have already established trust; providing detailed information about Lupus clinical trials in Lupus community offices and doctors' offices; and getting more diverse groups of people involved, including racial and ethnic minorities in medical and healthcare teams, were suggested as some of the ways to overcome these obstacles.
- One participant voiced the need to be transparent and educate people about their rights of dropping out of a clinical trial at any point and preserving their anonymity throughout the trial.
- One participant indicated that a first step to overcome the barrier was being offered clinical trials and having access to information about clinical trials. They mentioned that there is a misconception that certain racial ethnic minority groups do not want to participate in clinical trials, but the reason they do not participate is that they are not even being offered the opportunity to participate.
- Lack of support for minority groups was another issue mentioned by one participant, because in certain communities it is taboo to participate in clinical trials because of the clinical trial history of minority groups.
- One participant shared that the time commitment for traveling and taking time off from work to participate in a clinical trial is an issue that could be overcome by providing transportation, accommodations, and other initiatives.
- Two participants mentioned lack of health insurance is an issue. One participant specified minorities living in low-income housing, dependent on childcare, and welfare do not have health insurance. Another participant suggested the need for incentives to participate in 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? Why?

    - Three participants liked #1, "Join the Fight" the best, because it sounded welcoming and inclusive to them and had a positive feel to it. One of the participants noted that the word "diversity" in #1 indicated that the group involved in the clinical trials was open to all kinds of people, including racial and ethnic minority groups and asked all to come together and fight together. Another participant noted that it made them curious about what they would be a part of.
    - Two participants liked #3, "Take Charge," the best because it made them feel empowered and spoke to the individual directly.

    5b. Which do you like least? Why?

- Four participants liked #2, “Count Me In,” the least because it sounded bossy and passive to them. One participant disliked the part “Make sure” because it seemed to demand them to do something.
- One participant liked #1, “Join the Fight,” the least because of the word “fight.” They indicated that they have been already fighting and did not want to fight further. The word “Fight” was also perceived as being exhausting.
- One participant did not like any of the titles because the titles and taglines reminded them of WWII propaganda. They thought the taglines weren’t necessary and preferred to get to the point, which is increasing diversity and representation in Lupus clinical trials.

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

- For #1, “Join the Fight,” one participant would add the word “let’s” to the tag line to make it more welcoming and inclusive to everyone, “Join the fight and let’s increase diversity in Lupus research.” Two participants would change the word “and” to “to,” “Join the fight to increase diversity.” Three participants would not change anything.
- For #2, “Count Me In”, two participants preferred removing the part “like you” in the tag line because they felt that not just minorities, but everyone should be counted to make Lupus research more diverse and not only minority groups. Three participants would not change anything. Another participant would not include #2 in the list.
- For #3, “Take Charge”, one participant would not change anything. Two participants would add the word “let’s” in the beginning, “Let’s Take Charge.” One participant would change the word “and” to “to,” “Take charge to make Lupus research more diverse.” One participant disliked #3 and would not change anything. One participant would change #3 to “Take charge and include your part in making Lupus research more diverse.”

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?***

- A majority of participants indicated social media as their preferred source. Under social media, Twitter, Facebook, LinkedIn (to pass information across both organizational structures and individual contacts), and the Club House application were referenced by one participant.
- Three participants shared TV shows that have a diverse and large number of viewers as their preferred source. While waiting at doctor’s office, shows such as “The Price is Right,” “Judge Judy,” and midday talk shows were suggested, because they have a lot of advertisements. Shows with a large female audience such as Ellen, Oprah, and female-oriented channels, such as Lifetime or Oxygen, were also recommended. Two of the participants mentioned podcasts as a good source for hearing about Lupus clinical trials.
- Two participants indicated local advertisements at barber shops, beauty salons, supermarkets, outlets, coffeeshops, and restaurants as their preferred sources.

- Four participants indicated high-traffic areas and areas of transportation, such as bus stations and subways, as their preferred sources. One participant mentioned billboards in major cities where a lot of people travel as a good place to find out about Lupus clinical trials.

- Doctor's offices, churches, and pop-up advertisements were suggested by the participants as other sources to provide awareness.

- One participant articulated that they would like to see and hear about Lupus clinical trials everywhere because the more it is promoted, the more people would be willing to learn about Lupus.

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 indicated that they have multiple organs involved in addition to their Lupus.

- One participant mentioned the financial burden because of Lupus.

- One participant emphasized the urgency of more awareness of Lupus by people. They would like people to know that complications with Lupus, such as a blood clot, stroke, or heart attack, may cause patients to lose their lives.

- One participant expressed concern of experiencing flare-ups and fatigue because of Lupus. They noted that these symptoms take away from living life. Having the ability to not only manage chronic symptoms, but having a more productive life was preferred.

- Two participants indicated their interest in having access to holistic and complementary medicine options. One participant preferred taking fewer medicines with side effects.

Partner Organization

- 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 Rare Diseases, Pediatrics, Urologic and Reproductive Medicine, Division of Rare Diseases and Medical Genetics (DRDMG); Office of New Drugs, Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine, Division of Pharm Toxicology for Rare Diseases, Pediatrics, Urology, and Reproductive Medicine (DPTRDPURM); Office of Regulatory Policy, Division of Regulatory Policy III (DRPIII); 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); Office of Translational Sciences, Office of Clinical Pharmacology, Division of Translational & Precision Medicine (DTPM)

Patients Represented

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

- All patients and caregivers self-identified as belonging to a racial/ethnic minority group.
- A majority of patients expressed an interest in participating in clinical trials but had not participated.
- Patient ages ranged from 29 years old to 44 years old, and they were diagnosed between 6 and 23 years ago.

Prior to the Listening Session, Patients and Caregivers Shared

- A majority of the participants mentioned chronic fatigue as a major burden. Many also mentioned the financial burden and the pain.
- All patients indicated that they have never enrolled in a Lupus clinical trial before.

Financial Interest

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