

FDA Patient Listening Session on  
Pulmonary Sarcoidosis:  
*Stories for Progress*



Foundation for Sarcoidosis Research  
April 21, 2022

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# Foundation for Sarcoidosis Research

## About

The Foundation for Sarcoidosis Research (FSR) is the leading international organization dedicated to finding a cure for sarcoidosis and improving care for sarcoidosis patients through research, education, and support. FSR actively works with the world leading experts in sarcoidosis, investing in innovative, patient-centered research efforts and providing educational resources, support, and opportunities to accelerate research to patients worldwide.

Since its establishment in 2000, FSR has fostered over \$6 million in sarcoidosis-specific research initiatives. In an effort to grow the pipeline of sarcoidosis clinicians and researchers and to deepen the understanding of sarcoidosis, its causes, and its impact on the patients, FSR supports an annual fellowship, a pilot grant program, a multi-site Clinical Study Network, manifestation-specific grants, and critical innovative research to build a functional disease model to provide insights into the mechanisms of the disease and to allow for the exploration of the efficacy of potential drugs being explored for clinical trial.

Additionally, FSR is committed to keeping the patient at the center of clinical studies and trials. Through our clinical trial support and recruitment program, FSR has developed a robust curriculum aimed at assisting academic investigators and pharmaceutical companies in advancing clinical care improvement and drug development. FSR supports patient-driven feedback loops to help researchers and industry ensure that the patients' needs and desires are the main driving force for all trials. Furthermore, by ensuring timely patient recruitment, FSR reduces the time it takes to conduct a trial, and therefore, supports the acceleration of drug development.

In 2015, FSR launched our patient registry to expand the understanding of the patient journey and to better capture how sarcoidosis impacts quality of life and financial well-being. We now have over 5,000 participants in the registry and launched an annual survey to gather longitudinal data. We are currently looking into ways to expand the survey to further capture the mental and emotional burden of the disease.

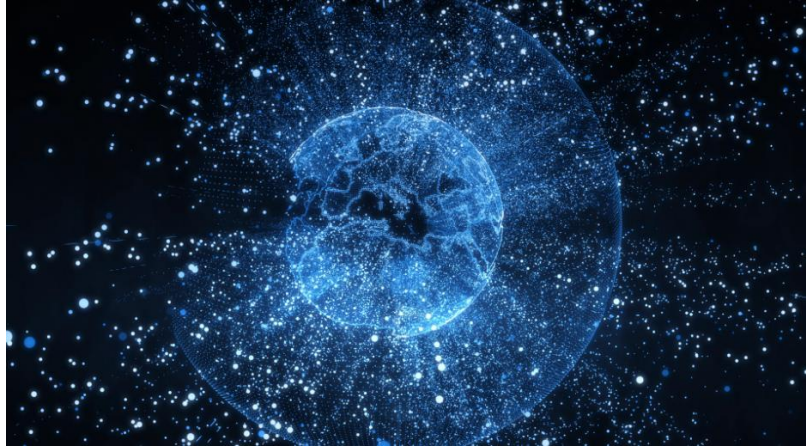
In addition to our efforts to drive research forward, FSR remains committed to providing patients with much-needed community and educational tools to further their understanding of how to live with this complex rare disease. FSR has developed a number of tools aimed at empowering and amplifying the patient voice including our Patient Advisory Committee, Speakers Bureau, and our Women of Color Patient Advisory Committee. Each of these groups help drive patient awareness, educational programming, community outreach, and marketing, as well as serving as a sounding board for researchers and industry looking to better understand the sarcoidosis journey. Additionally, FSR has developed a comprehensive volunteer program replete with 99 community-level volunteers, virtual support groups, and 1:1 peer support for those newly diagnosed or dealing with the complexities of a flare or new manifestation of the disease. Finally, FSR offers extensive educational programming to patients and clinicians in order to improve diagnosis, treatment management, and provides resources to support those living with sarcoidosis.

## Background

### What is Sarcoidosis

Sarcoidosis (pronounced SAR-COY-DOE-SIS) is an inflammatory disease of unknown cause characterized by the formation of granulomas—tiny clumps of inflammatory cells—in one or more organs of the body. Approximately 5-10% of all patients diagnosed will suffer from advanced sarcoidosis. While several off-label treatments have been proposed for these individuals, including recommendations based on the involved organs<sup>12</sup>, more research into the effectiveness of these treatments is required.

Despite increasing advancements in research, sarcoidosis remains difficult to diagnose, with limited treatment options, and no known cure.<sup>3</sup> The clinical presentation of sarcoidosis depends on the intensity and duration of the inflammation and the organs involved. Sarcoidosis may spontaneously remit or it may result in chronic inflammation, which can be complicated by irreversible organ damage, fibrosis, and sometimes complete organ failure.<sup>4</sup> The estimate prevalence of sarcoidosis in the US ranges between 150,000 and 200,000<sup>5</sup>, with an estimated 1.2 million individuals with sarcoidosis worldwide.



Patients suffering from advanced sarcoidosis include those with chronic disease (active disease for more than 2-5 years), who have worsening disease symptoms despite treatment with prednisone and with other second and third line therapies. Those with advanced sarcoidosis are often treated with therapies not approved by the FDA and require prolonged treatment to manage symptoms. To reduce the inflammation, the long-term impact of the disease, and its impact on patients' quality of life, physicians must balance the need for therapies with the costs of side effects.

<sup>1</sup> Baughman, R. P., Valeyre, D., & Korsten, P. (2021). ERS clinical practice guidelines on treatment of sarcoidosis. *Eur Respir J*; in press <https://doi.org/10.1183/13993003.04079-2020>

<sup>2</sup> Diagnosis and Detection of Sarcoidosis. An Official American Thoracic Society Clinical Practice Guideline Crouser, E. D., Maier, L. A., Wilson, K. C., Bonham, C. A., Morgenthau, A. S., Patterson, K. C., Abston, E., Bernstein, R. C., Blankstein, R., Chen, E. S., Culver, D. A., Drake, W., Drent, M., Gerke, A. K., Ghobrial, M., Govender, P., Hamzeh, N., James, W. E., Judson, M. A., . . . Baughman, R. P. (2020). Diagnosis and Detection of Sarcoidosis. An Official American Thoracic Society Clinical Practice Guideline. *Am J Respir Crit Care Med*, 201(8), e26–e51. <https://doi.org/10.1164/rccm.202002-0251ST>

<sup>3</sup> Hunninghake GW, Costabel U, Ando M, Baughman R, Cordier JF, du Bois R, Eklund A, Kitaichi M, Lynch J, Rizzato G, et al. ATS/ERS/WASOG statement on sarcoidosis. American Thoracic Society/ European Respiratory Society/World Association of Sarcoidosis and Other Granulomatous Disorders. *Sarcoidosis Vasc Diffuse Lung Dis* 1999;16:149–173

<sup>4</sup> Drent, M., Crouser, E. D., & Grunewald, J. (2021). Challenges of Sarcoidosis and Its Management. *New England Journal of Medicine*, 385(11), 1018–1032. <https://doi.org/10.1056/nejmra2101555>

<sup>5</sup> Baughman R, Field S, Costabel U, Crystal R, Culver DA, Drent M, Judson, Wolff G. (2016). Sarcoidosis in America. Analysis Based on Health Care Use. *Ann Am Thorac Soc*. Aug;13(8):1244-52. DOI: [10.1513/AnnalsATS.201511-760OC](https://doi.org/10.1513/AnnalsATS.201511-760OC)

## Pulmonary Sarcoidosis

Sarcoidosis affects the lungs in approximately 90% of cases, but it can affect almost any organ in the body and in more advanced or chronic cases can impact multiple organs at the same time. Although sarcoidosis presents in a variety of different ways, common symptoms associated with pulmonary sarcoidosis include cough, shortness of breath, chest pain, and most commonly, extreme fatigue.<sup>6</sup>

Approximately 10% to 30% of patients with sarcoidosis develop a progressive form of pulmonary sarcoidosis. The mortality rate for progressive sarcoidosis is approximately 7% over a 5-year period. However, excluding Japan which has a higher incidence of death from cardiac sarcoidosis, over 60% of deaths from sarcoidosis around the world are tied directly to pulmonary involvement. Two complications that are associated with an advanced form of pulmonary sarcoidosis are interstitial lung disease and sarcoidosis-associated pulmonary hypertension.<sup>7</sup>



## Other Manifestations

Extrapulmonary sarcoidosis can manifest before, concurrently, or after the pulmonary manifestations. In about 10% of the cases the lungs do not become involved. Extrapulmonary sarcoidosis can manifest in any organ of the body, as well as multiple organs at the same time.<sup>8</sup>

Cutaneous sarcoidosis occurs in approximately 20-30% of the cases,<sup>9</sup> eyes are involved in an estimated 10-60% of patients (with a higher incidence in African Americans), neurosarcoidosis occurs in just 5% of the cases, additionally sarcoidosis can impact the liver, kidneys, joints bones, and muscles.<sup>10</sup> Finally, it is estimated that in the US, about 5% of patients with sarcoidosis are diagnosed with cardiac sarcoidosis. This number is not believed to be truly reflective of the number of cases because on autopsy approximately 20% to 30% of patients with other forms of sarcoidosis are found to also have cardiac sarcoidosis.<sup>11</sup>

<sup>6</sup> Ibid.

<sup>7</sup> Belperio JA, Shaikh F; Abtin FA; et al (2022). Diagnosis and Treatment of Pulmonary Sarcoidosis: A Review *JAMA*. 2022;327(9):856-867. [doi:10.1001/jama.2022.1570](https://doi.org/10.1001/jama.2022.1570)

<sup>8</sup> Baughman, Sarcoidosis in America. Analysis Based on Health Care Use.

<sup>9</sup> Haimovic A, Sanchez M, Judson MA, et al. Sarcoidosis: a comprehensive review and update for the dermatologist: part I. Cutaneous disease. *J Am Acad Dermatol*. 2012;66:699.e1–e18.

<sup>10</sup> Rao DA, Dellaripa PF. Extrapulmonary manifestations of sarcoidosis. *Rheum Dis Clin North Am*. 2013;39(2):277-297. [doi:10.1016/j.rdc.2013.02.007](https://doi.org/10.1016/j.rdc.2013.02.007)

<sup>11</sup> Mehta D, Lubitz SA, Frankel Z, et al. Cardiac involvement in patients with sarcoidosis: diagnostic and prognostic value of outpatient testing. *Chest*. 2008;133:1426–35. DOI: [10.1378/chest.07-2784](https://doi.org/10.1378/chest.07-2784)

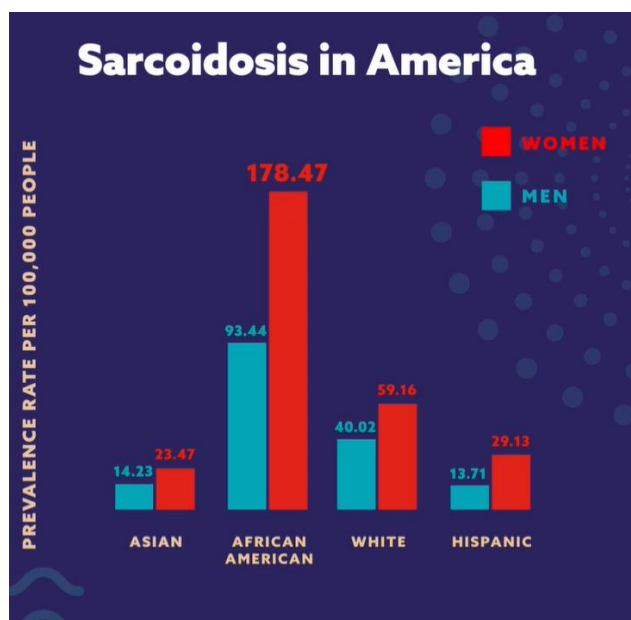
## Demographics

There are incidences of sarcoidosis all around the globe. Sarcoidosis can impact any race, ethnicity, and gender. Although sarcoidosis can affect people of all ages, it most commonly develops in middle-aged adults – for men peak age of incidence is between 30-50 years of age and for women peak age is between 50-60 years of age.<sup>12</sup>

Women have a slightly higher prevalence of the disease; however, African Americans have an almost 2:1 prevalence.<sup>13</sup>

Although sarcoidosis requires both a genetic predisposition and an environmental, occupational, and/or microbial exposure, there is a correlation of risk that increases by a factor of 3.7 when a person has at least one first-degree relative who is impacted.<sup>14</sup>

African American women experience the highest incidence of sarcoidosis in the US compared to any other group. They are more likely to experience chronic and severe symptoms and higher hospitalization rates than Caucasians and more than double that of African American men. Additionally, their sarcoidosis-related mortality rate is 12 times higher than that of Caucasians and 1.5 times higher than that of African American men.<sup>15</sup>



## Patient Listening Session Overview

Patient listening sessions are small, informal, non-regulatory, non-public discussions from the patient perspective that seek to deepen the FDA's understanding of diseases or health conditions, the burden of the disease or health condition on those it impacts, and not about specific medical products (drug, biologic or device).

Building on feedback FSR gathered from surveys of patients, clinicians, researchers, and industry partners, we shared stories and data to highlight our priorities for the FDA.

- Providing support for the identification and approval of better tools for early diagnosis of sarcoidosis
- Recognizing the urgency for the development of better therapies
- Taking a broader approach in defining acceptable data, outcome measures, trial requirements, and endpoint selection
- Working with FSR and other rare disease organizations to identify paths, like decentralized trials, to ensure clinical trial representation of the population that is underserved and disproportionately impacted

<sup>12</sup> Drent, Challenges of Sarcoidosis and Its Management

<sup>13</sup> Ungprasert P, Ryu JH, Matteson EL. Clinical Manifestations, Diagnosis, and Treatment of Sarcoidosis. *Mayo Clin Proc Innov Qual Outcomes*. 2019;3(3):358-375. Published 2019 Aug 2. [doi:10.1016/j.mayocpiqo.2019.04.006](https://doi.org/10.1016/j.mayocpiqo.2019.04.006)

<sup>14</sup> Ibid.

<sup>15</sup>

## Who Participated

During this closed-door session, FSR's CEO, six patients, one caregiver, and one medical expert from FSR's Scientific Advisory Board Member, Lisa Maier, MD, from National Jewish Hospital framed the issues and shared stories about their journeys, trials, and needs for better therapies. This session was heavily attended by the FDA and covered a wide array of FDA focus areas. A total of 50 participants from the FDA attended this listening session. Attendees represented 16 different offices from across 5 FDA Centers. This session was also observed by the FSR Board President and Scientific Advisory Board Chair.

### **Office of the Commissioner (OC) – 3 offices**

- OC/OCPP/OPA – Office of Clinical Policy and Programs/Office of Patient Affairs (*organizer*)
- OC/OCPP/OCP – Office of Clinical Policy and Programs/Office of Clinical Policy
- OC/OCPP/OOPD – Office of Clinical Policy and Programs/Office of Orphan Products Development

### **Office of Regulatory Affairs (ORA) – 1 office**

- ORA/ORS/OMPTSLO/NMPL – Office of Regulatory Science/Office of Medical Products and Tobacco and Specialty Laboratory Operations/Northeast Medical Products Laboratory

### **Center for Biologics Evaluation and Research (CBER) – 3 offices/divisions**

- CBER/OCD – Office of the Center Director
- CBER/OTAT/DCEPT/GMBI – Office of Tissues and Advanced Therapies/Division of Clinical Evaluation and Pharmacology/Toxicology/General Medicine Branch I
- CBER/OTAT/DCEPT/GMBII – Office of Tissues and Advanced Therapies/Division of Clinical Evaluation and Pharmacology/Toxicology/General Medicine Branch II

### **Center for Devices and Radiological Health (CDRH) – 3 offices/divisions**

- CDRH/OPEQ/OHTI/DHTIC – Office of Product Evaluation and Quality/Office of Health Technology I /Division of Health Technology I C
- CDRH/OPEQ/OHTII/DHTIIIA – Office of Product Evaluation and Quality/Office of Health Technology II/Division of Health Technology III A
- CDRH/OPEQ/OHTIII – Office of Product Evaluation and Quality/Office of Health Technology III

### **Center for Drug Evaluation and Research (CDER) – 6 offices/divisions**

- CDER/OND/OII/DPACC – Office of New Drugs/Office of Immunology and Inflammation/Division of Pulmonology, Allergy, and Critical Care
- CDER/OND/OII/DPTII – Office of New Drugs/Office of Immunology and Inflammation/Division of Pharmacology Toxicology for Immunology and Inflammation
- CDER/OND/ORDPURM/DRDMG – Office of New Drugs/Office of Regulatory Operations/Division of Regulatory Operations for Immunology and Inflammation
- CDER/OPQ/OND/DNDPIII/NDPBV – Office of Pharmaceutical Quality/Office of New Drug Products/Division of New Drug Products Branch V
- CDER/OTS/OB/DBIII – Office of Translational Sciences/Office of Biostatistics/Division of Biometrics III
- CDER/OTS/OCP/DIIP – Office of Translational Sciences/Office of Clinical Pharmacology/Division of Inflammation and Immune Pharmacology

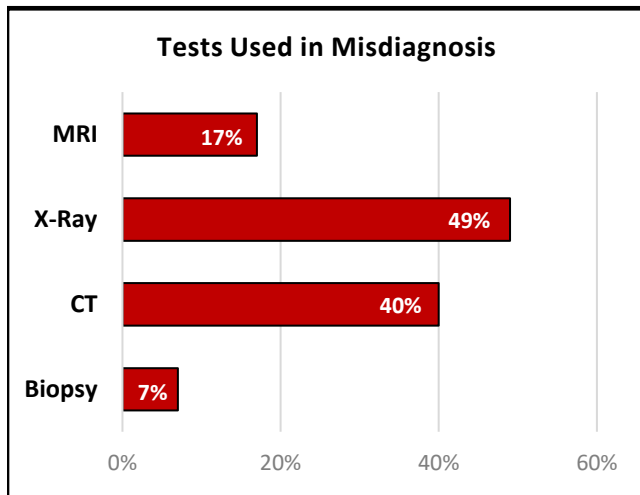
## Better tools for early diagnosis of sarcoidosis

*“I have been from doctor to doctor. I have spent most of the last ten years in absolute agony. “*

-Anonymous, patient living with sarcoidosis

The diagnostic journey to sarcoidosis is long and fraught with misinformation. Inaccurate and imprecise diagnostic tools and the lack of biomarkers, translate to lost years of care and irreversible damage to organs. Misdiagnosis increases worry and can severely impact mental health.

Our patient survey revealed that 32% of those diagnosed with sarcoidosis experienced at least a four year delay before receiving an accurate diagnosis and as many as 12% of patients waited 8 years or longer for a definitive diagnosis path. Advanced technology such as X-rays, CTs, MRIs and even biopsy have failed patients again and again. In fact, 35% of patients surveyed received treatment for cancer before receiving their sarcoidosis diagnosis.



During this session, patient speakers shared stories of their circuitous route in navigating the health care system. Jim shared that he went through 3 years without the correct diagnosis, and was even diagnosed with lymphoma and had two open chest biopsies before finally learning it was an advanced stage sarcoidosis.

Kathryn, a patient with sarcoidosis and a US veteran, spoke of her 10-year quest for a diagnosis. She emphasized her exposure to test after test and the disappointment, self-doubt and depression that came from this lack of diagnosis. She strongly urged the FDA to consider and approve diagnostic tools that can address diagnosis with “real-time technology.”

Another patient, Andrew, spoke of the paralyzing fear that came with an inaccurate diagnosis that left him believing his disease had progressed beyond hope. He highlighted that his path to an accurate diagnosis was illuminated not by the healthcare system but by his wife’s pre-established connections. He warned that, “Not everyone, in fact most, aren’t fortunate [enough] to have [this type] of network to tap into.” Like, Kathryn, he shared how misdiagnosis brought him into a “dark space” and urged the FDA to pursue alternative options to improve this path.

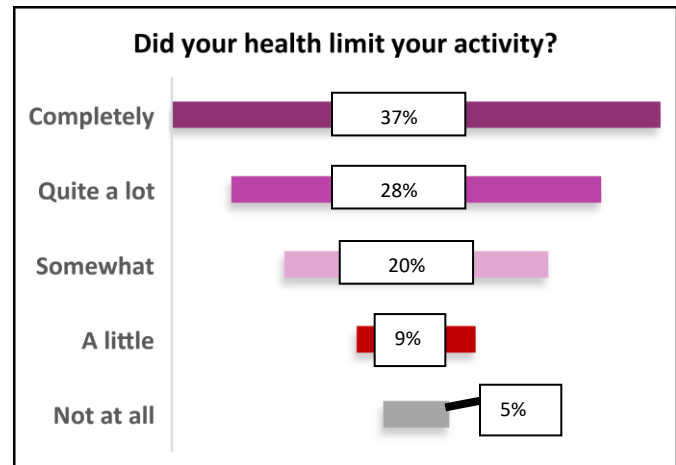
## The Burden of the Disease

*“We have had to give up on so many of our dreams over the last 8 years as I have watched sarcoidosis chip away at my husband bit by bit.”*

-Jean, Sarcoidosis Caregiver

Living with chronic, complex forms of sarcoidosis comes with significant burdens. 95% of sarcoidosis patients surveyed indicated that their activities were limited as a result of living with the disease. 76% of patients noted that their family finances were impacted by their disease and 56% noted that they needed to leave a job due to their diagnosis.

Sarcoidosis strikes most patients in the prime of their lives, most commonly being diagnosed in an individual’s late 30’s to early 50’s. This is the time of peak earning potential of individuals and the time of highest family costs for those raising children. In addition, the financial burden mental burden of the disease must not be overlooked. 66% of respondents in FSR’s Patient Registry noted that they feel depressed as a result of living with sarcoidosis day in and day out.



Patient speakers, Jim, Heidi, Erica and Andrew, all shared stories of how the disease impacted their career trajectories. Both Heidi and Jim spoke of being forced into early retirement and leaving careers they loved due the crushing fatigue and overwhelming symptoms of the disease. Erica and Andrew spoke of the complexities that have resulted from symptoms flaring during work and work events.

Multiple patient speakers shared with the FDA how the strain of living with this chronic disease negatively impacted their social relationships leading to divorces, lost friendships, and increased isolation. Patients spoke of fear and anxiety that came with not knowing when or how their disease might progress and not knowing if the therapies would work. Patients spoke of depression that came from being unable to “show up” for their children or spouses at critical times due to flares and medication side-effects.

*“I have been forced to give up so many things that I love because of what is happening to me – gardening, travel, friends, family events – just to name a few. I cannot tell you how many times I have sat at home alone on Christmas Eve while my family went to church and holiday parties, all because I simply cannot function after 5 or 6 o’clock.”*  
-Jim, Sarcoidosis Patient

Furthermore, sarcoidosis is a disease of disparities. As Dr. Lisa Maier, FSR Scientific Advisory Board Member and Professor and Chief, Division of Environmental and Occupational Health Sciences at National Jewish Health and University of Colorado, noted, “the burden of the disease is exponentially more impactful on African Americans, and in particular African American women.” These patients experience higher rates of hospitalization, higher rate of disability, lower quality of life, and increased mortality. During this session she discussed the need to close these gaps and develop more equitable paths for diagnostics and drug development.

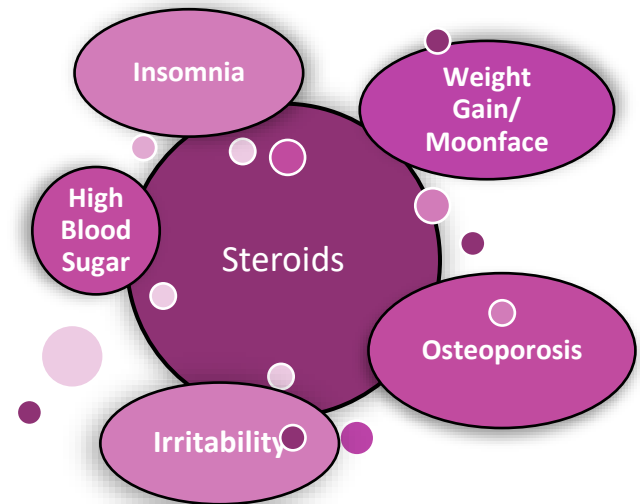


## The Need for Better Therapies

*“Steroids are the devil. Make more medications available that will reduce the number of steroids and let me feel better!”*

-Anonymous, Sarcoidosis Patient

Steroids/Corticosteroids are often deployed as the first-line of treatment for sarcoidosis. In a survey conducted by FSR, 99% of patients who were treated for sarcoidosis were treated with steroids at some point in their therapeutic journey. As Dr. Maier explained to the FDA, “There is a need for better therapies with fewer side effects than corticosteroids.” The most commonly reported side effects reported in the patient survey were a significantly rounded face often called moon face (59% of respondents), insomnia (54% of respondents), irritability (48% of respondents), and extreme weight gain (43% of respondents). Other side effects included water retention, osteoporosis, increased blood sugar, diabetes, gastrointestinal issues,



increased blood pressure, and heart palpitations. Additionally, Dr. Maier explained that a recent literature review noted that *“Even a year of steroids can cause cardiovascular side-effects including AFIB. They also cause a lower quality of life for those being treated with over 500mg of steroids throughout their lifetime. Corticosteroids are the driver of this problem, not the disease.”*<sup>16 17</sup>

The patient speakers echoed the sentiments of the community by highlighting the ways that steroids impacted their mood and body. Andrew noted, that while on steroids he couldn’t sleep, he became anxious and “snappy,” and that his eyes and teeth were permanently damaged by his steroid use. Jim shared stories of his severe migraines and dramatic weight gain. Heidi shared that because of limited therapies her “prednisone band aid has gotten larger and larger over these years,” and how she is now “battling insomnia, anxiousness, depression, bone loss, and muscle weakness as a result.” Jessica shared the alarming list of side effects she has experienced including: 80-pound weight gain, stomach bloating to the point of looking pregnant, insomnia, depression, mood swings, irritability, bone density loss, increased sweating, vision changes and hair loss. Jessica noted that though steroids are inexpensive, the cost for the patient is too high. She urged the FDA to help advance drug approval noting that *“We can’t wait! We need new drug therapies now!”* She told them, *“Please do not make us continue to decide between fighting sarcoidosis and fighting steroids.”*

<sup>16</sup> Khan, N. A., Donatelli, C. V., Tonelli, A. R., Wiesen, J., Ribeiro Neto, M. L., Sahoo, D., & Culver, D. A. (2017). Toxicity risk from glucocorticoids in sarcoidosis patients. *Respiratory Medicine*, 132, 9–14. <https://doi.org/10.1016/j.rmed.2017.09.003>

<sup>17</sup> Pujades-Rodriguez, M., Morgan, A. W., Cubbon, R. M., & Wu, J. (2020). Dose-dependent oral glucocorticoid cardiovascular risks in people with immune-mediated inflammatory diseases: A population-based cohort study. *PLOS Medicine*, 17(12), e1003432. <https://doi.org/10.1371/journal.pmed.1003432>

*Because so many drugs are used off label to treat sarcoidosis it creates a wild west of insurance denials and extreme costs out-of-pocket. It's hard to continually fight this fight when you are already exhausted and sick from the disease.*

**-Heidi, Sarcoidosis Patient**

Heidi and Jim spoke of the many other non-FDA approved therapies that they and their doctors have tried to manage the disease over the years. They spoke of the roller coaster associated with holding out hope that this new therapy would be the one to keep symptoms under control.

They sounded the alarm with the FDA, sharing the need for “more tools” and “a wider arsenal.” They recommended the FDA broaden its thinking to consider not only new therapies but incentivizing drug repurposing to allow for “swifter paths” to drug development.

## Better Pathways to Drug Development

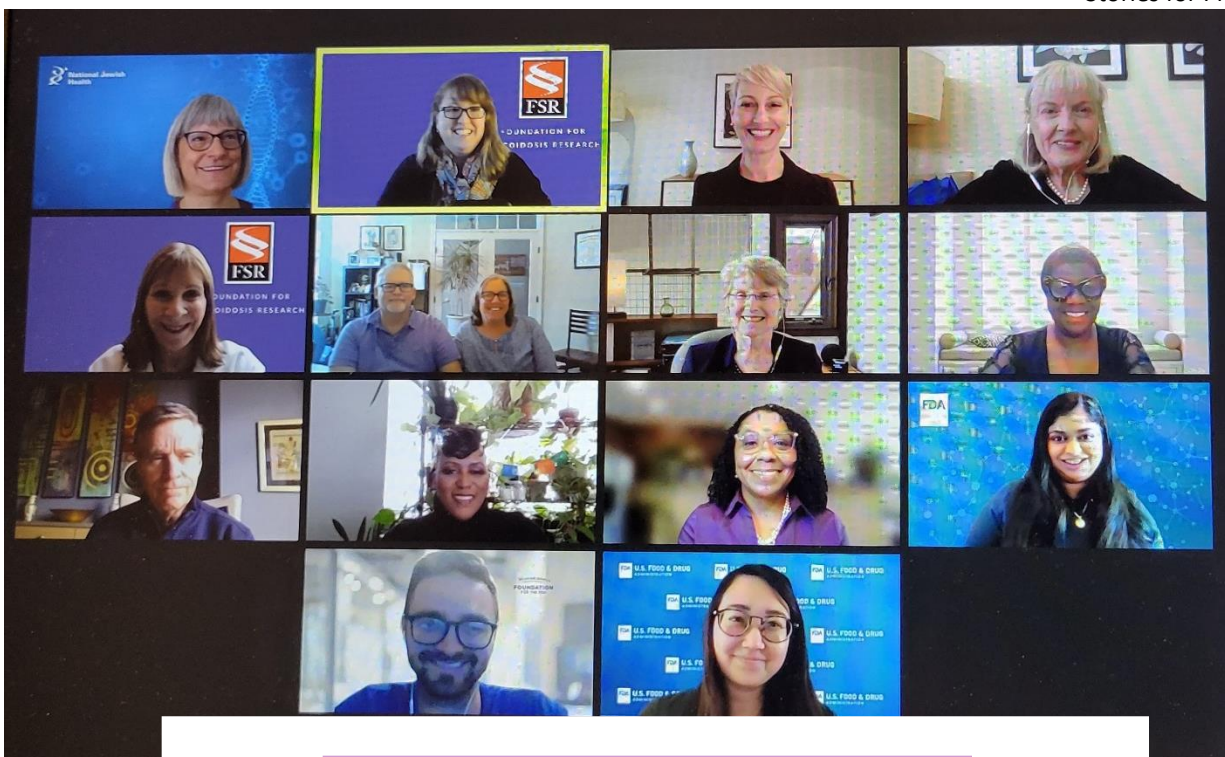
During this session, we called on the FDA to develop better scaffolding around clinical use of therapies for the treatment of sarcoidosis, through the data provided for these drugs in other similar disease areas. We urged the FDA to consider ways to broaden the incentive for manufacturers to seek new indications for existing therapies.

Dr. Maier noted that sarcoidosis is lagging behind in research funding and is in need of more federal support. She noted that only 2% of NHLBI funding has been dedicated to sarcoidosis research, while other conditions, like pulmonary arterial hypertension and pulmonary fibrosis, that impact a similar number of individuals have greater than 15% of the funding dedicated to their advancement. As a result of this lack of funding, we lack understanding of the diseases cause, manifestations, and natural history of the disease.

With this in mind, we urged the FDA to take a broader approach to acceptable data, trial requirements, and endpoint selection. Sarcoidosis is often called the snowflake disease because “no two patients’ disease progresses in the same way.” For sarcoidosis trials, it is essential to have flexible pathways to trial approval to allow for the inclusion of those with complex disease in the trial, smaller numbers of participants, and endpoints that are more responsive to the patients’ needs.

FSR and patient speakers asked the FDA to be innovative and to pave the way for the inclusion of complexity in trial design. We believe the FDA needs a paradigm shift much like the shift that happened to allow women in clinical trials. We can’t ignore the complexity of the disease for desire of “clean data,” rather it is imperative we evolve our definition of what is good data to encompass complexity. For trials to be accurate and impactful they must allow for complexity and include those most severely impacted.

Additionally, one of the patient speakers, Erica, emphasized the need for decentralized trial options in order to better accommodate the needs of underserved populations. Furthermore, she urged the FDA to allow for more responsive endpoints to make trials more accessible and responsive to patients. She stated that “clinical trials [should consistently] check-in with patients to discuss not only their reaction to the drug, but their mental health status...are imperative to improving representation in trials.”



## Conclusion

We must develop a deeper understanding of the mechanism and causes of sarcoidosis. We must develop and identify advanced diagnostic tools for earlier treatment. And, we must expand the treatment options beyond steroids.

Sarcoidosis is a complex, multi-organ, multisystem disease. There has been an undue burden of proof for clinical trials under the current assessment mechanisms. We call on the FDA to broaden the definition of “good data” to allow for clinical trials that are more reflective of those impacted by the disease. We urge the FDA to allow for alternative endpoints that show meaningful impact to patients impacted by the disease. And we ask the FDA to consider more flexibility around the number of participants, the type of acceptable real-world data, and outcomes data to allow for advancement of drug development in this space.

FSR would like to thank the FDA for the opportunity to share these concerns and we look forward to working with the organization in the development of better diagnostic tools, advancement of better treatments, and new and innovative approaches to clinical trial design.

**This FDA Listening Session was made possible by a grant from  
The Gies Foundation.**

## Disclaimer

*Discussions in FDA Patient Listening Sessions are informal. All opinions, recommendations, and proposals are unofficial and nonbinding on FDA and all other participants. This report reflects FSR's account of the perspectives of patients and caregivers who participated in the Patient Listening Session with the FDA. To the extent possible, the terms used in this summary to describe specific manifestations of sarcoidosis health effects and impacts, and treatment experiences, reflect those of the participants. This report is not meant to be representative of the views and experiences of the entire sarcoidosis patient population or any specific group of individuals or entities. There may be experiences that are not mentioned in this report.*

**To learn more about  
Foundation for Sarcoidosis Research (FSR)  
and our efforts to improve diagnosis pathways, treatments, and  
to accelerate drug development,  
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