

FSR Clinical Education & Engagement Series

Fostering Collaboration to Inspire Progress



Advancing Sarcoidosis Clinical Trials and Research - Clinical Education and Engagement Interactive Workshop



FOUNDATION FOR
SARCOIDOSIS RESEARCH

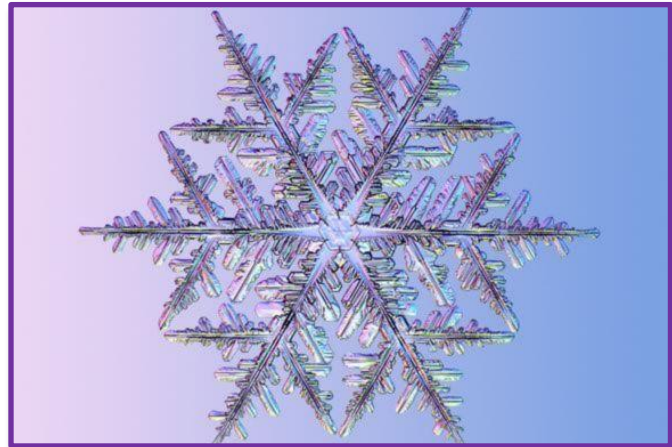


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Background

Sarcoidosis (Pronounced

SAR-COY-DOE-SIS) is an inflammatory disease characterized by the formation of granulomas—tiny clumps of inflammatory cells—in one or more organs of the body. When the immune system goes into overdrive and too many of these clumps form, they can interfere with an organ’s structure and function. When left untreated, chronic inflammation can lead to fibrosis, which is the permanent scarring of organ tissue and chronic inflammation can result in systemic symptoms like chronic fatigue. This disorder affects the lungs in approximately 90% of cases, but it can affect almost any organ in the body.



It is estimated that the prevalence of sarcoidosis in the US ranges between 150,000 and 200,000¹ with an estimated 1.2 million individuals with sarcoidosis worldwide². African American women are 3x more likely to develop sarcoidosis than white women and white men.

For far too long, sarcoidosis has been an afterthought in research and drug development. Foundation for Sarcoidosis Research (FSR) has taken the lead to build bridges between pharmaceutical companies and academic researchers to help identify meaningful therapeutic and diagnostic pathways and to de-risk the path for clinical trials.

Sources

Baughman RP, et al. *Ann Am Thorac Soc*. 2016;13:1244–1252.
Denning DW, et al. *Eur Respir J*. 2013;41:621-626.

Through the creation and support of the [FSR Global Sarcoidosis Clinic Alliance \(FSR-GSCA\)](#), a member program consisting of clinics, hospitals, individual providers, patients, and caregivers committed to finding a cure and offering evidence-based, patient-centric care for those living with sarcoidosis, FSR has built a network of 43 leading academic institutions committed to working collaboratively to advance best practice and improve patient outcomes. Over the years, FSR has established strong relationships with the US Food and Drug Administration (FDA) and the National Institutes of Health (NIH) to help create better pathways to accelerate and advance sarcoidosis research and to help pave the way to better therapies and drug approval.



“Now is the time for sarcoidosis. We are on the precipice of significant progress. More clinicians and researchers are committing to the field than ever before. Through the FSR- GSCA we are building the infrastructure for global partnerships



and best practice sharing,” said Mary McGowan, FSR CEO. FSR-supported research in omics, biomarker identification, and disease model creation have helped us to deepen our understanding of the disease mechanisms, potential therapeutic pathways, and understanding of why some forms of sarcoidosis advance into multi-system sarcoidosis while others level out, remit or seem to improve over time. And, now, pharmaceutical and industry partners have joined into these efforts in unprecedented numbers.

In the last 3 years, over 1,500 patients have sought out information and completed pre-screeners about sarcoidosis clinical trials, raising their hands to participate to help advance science and to bring us one step closer to better therapies and a possible cure.

- Data from FSR's sarcoidosis clinic trial recruitment efforts

Patients are listening, seeking out information, and showing up to participate in support of developing potential new therapies.

Despite all the efforts by clinicians, patients, and FSR, there remains a number of significant barriers to clinical trial success. Institutional barriers include start-up delays for new trials, an inability or unwillingness to accept prospective patient referrals outside of

their institution's patients, and a lack of experienced and dedicated coordinators and other team support. Researchers, working closely with the FDA, have investigated to identify valid endpoints, functional eligibility criteria, and the most meaningful data analysis strategies reflective of the needs of the sarcoidosis community.

We know that there are deep rooted systemic challenges that will require years of work to change. It is our belief that through collaboration and candid conversations we can shave years off the long research and development processes. Patients have no time to delay their treatment options. They need better treatments now and we owe patients our very best efforts to make this happen quickly and effectively.

To that end, on November 9, 2023, FSR hosted a two-and-half-hour session with leading research experts in the field from both site study teams and industry sponsors, to identify new and creative solutions to address these barriers head-on. Below are the reflections and learnings from this groundbreaking session. Together we can change the course of this disease.

We Need New Therapies Today – The Patient Perspective

The success of clinical trials is of the utmost importance for patients like Heidi Junk, FSR Board Member, FSR Patient Advocate, FSR Patient Navigator, and woman living with pulmonary and neurosarcoidosis. Like so many other patients living and struggling with sarcoidosis, Heidi shared why the success of research and clinical trials matters so much to those living with this complex disease.



Heidi's journey, like so many others, started out with the hope that currently known therapies would heal her, relieve her symptoms of breathlessness, fatigue, joint pain, and nerve pain. However, therapy after therapy has failed. Each off-label

"I am desperate for more treatments and better quality of life."

-Heidi, Patient Living with Sarcoidosis

therapy attempt came with the added burden of months of fighting insurance companies. Without a clearer understanding of the cause of her sarcoidosis and lack of biomarkers for identifying her potential to progress, expert clinicians were left with a process of trial and error. Even as some of the therapies identified worked, some only helped a little while others

worked for only a short period of time. Today, Heidi has reached the very last drug on the list of potential therapies and is relying on high doses of steroids to reduce the inflammation. The long-term side effects are real and Heidi fears that her body may not be able to survive much more.

Despite all of these challenges, Heidi and her fellow sarcoidosis patients have faith in the science. They have hope and believe that “trials happening now are the path to the future.” Heidi calls on all of us to “seize this moment.” She notes that we have come so far, and that she and so many patients like her are ready to do whatever is necessary to drive this forward. Heidi is calling on all of you to put up the good fight and to come together at this moment in time to push us forward in the hopes of better therapy and outcomes for all patients.

“While I waited for insurance approval, my sarcoidosis, of course, did not wait and I had to endure 10/10 nerve pain over many months waiting for the approval of one drug and over a year and half for the approval of another.”

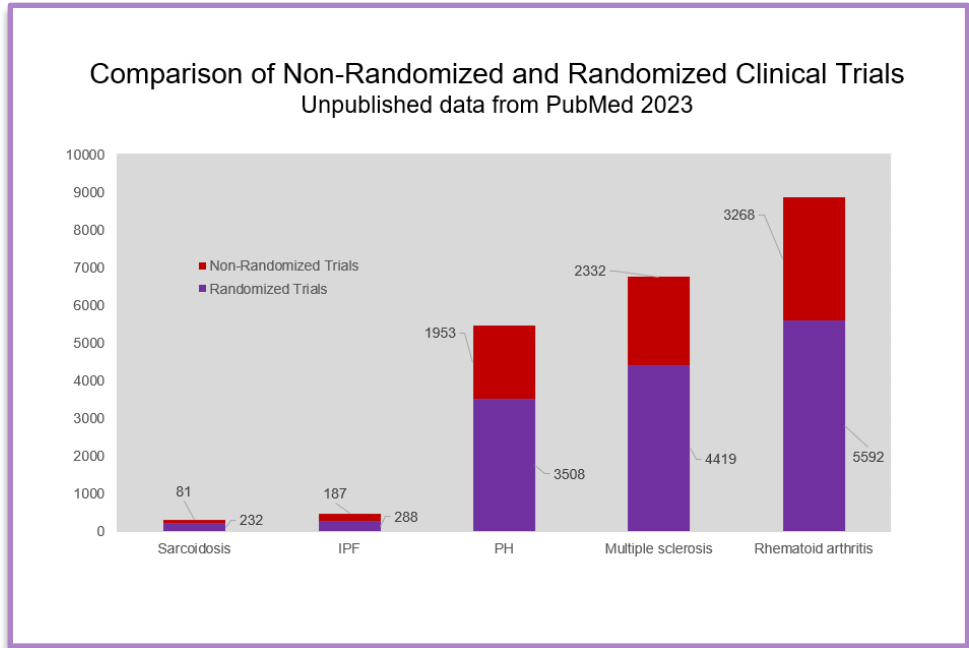
-Heidi, patient living with sarcoidosis

We Are At a Crucial Time for Sarcoidosis

Keynote speaker, Daniel Culver, DO, framed the discussion this way, “We are at a crucial time for sarcoidosis...we can either make our clinical trials successful or we can go back to where we were 15 years ago with no interest in clinical trials and limited pharmaceutical engagement at the rate of one trial every 10-15 years.”



Although there is a long list of potential off-label therapies to try when treating a patient with sarcoidosis, there is very little evidence of efficacy, and even when trials have been conducted, the trial design precludes further drug approval. It is important to support randomized double blinded trials, pre-clinical analysis, and therapeutic testing to ensure that we not only advance current potential therapies but so we can design better trials and identify other potential therapies in the future. Furthermore, FDA approval is an important goal not only because it brings forth new potential therapies, but also because it brings with it more investment, attention, awareness, funding, and more science.



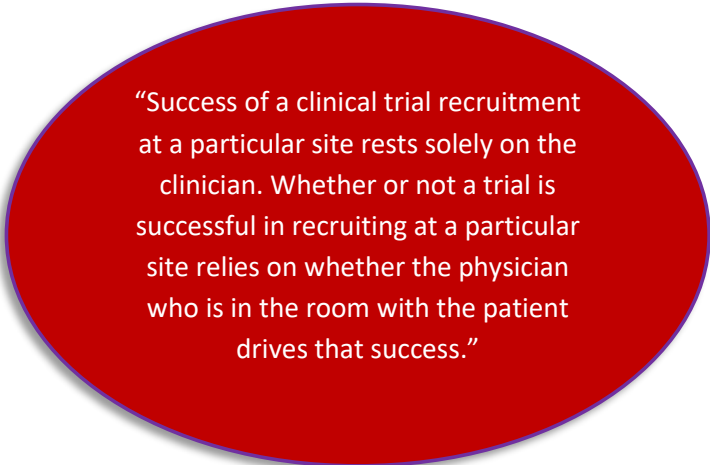
Sarcoidosis lags significantly behind sister diseases with similar prevalence such as rheumatoid arthritis, multiple sclerosis, and Crohn’s disease in the number of randomized clinical trials taking place. There are a number of barriers to clinical trials that need to be addressed if we hope to have more FDA-approved treatment options: 1) many clinicians who don’t treat sarcoidosis patients daily think that sarcoidosis mostly remits; 2) sarcoidosis disproportionately impacts under-represented and under-resourced patients, impacting groups that already face significant bias in medicine; 3) there is a belief by some that the therapies we have are “pretty good,” resulting in a mindset that there is no need for better therapies; 4) we have a limited understanding of the science and mechanism of the disease; 5) there is not a clear regulatory approval pathway; 6) the disease is very complex and heterogenic; 7) there are no validated clinical outcome measures; and 8) enrollment for clinical trials can be very difficult.

Dr. Culver notes that clinicians have responsibility in this lack of advancement due to 1) accepting less than rigorous evidence for use of off-label therapies, 2) allowing for inadequate study design from sponsors looking to come into this space, and 3) in accepting insufficient pre-clinical work which shapes the understanding of the mechanism of the disease.

We must tackle myths and misunderstandings about sarcoidosis and the population it impacts. Spontaneous remission during the interval usually covered by a trial is not as prevalent as initially believed but has wrongly been a defining characteristic when shaping the trial populations and eligibility criteria. In defining the population, we need to move more towards predicting what will happen in the future, rather than relying on what has happened in the past when considering enriching the populations for trials using precision approaches. When considering patients as trial candidates, we must consider using treatment naïve populations. We must broaden the pool of potential patients by keying into the ways that clinicians are currently treating patients.

We must be open to new clinical outcome measures. Forced Vital Capacity (FVC) works as an endpoint for many lung diseases but is not particularly helpful in measuring the impact of therapies in sarcoidosis. Endpoints should be more responsive to the desire and needs of the patient population, aligning better with how the patient feels, functions, and survives. Current Patient Reported Outcomes (PROs) need more validation work before they will be accepted by regulators. Endpoints should align with the expected effect of the therapy, should be easily measurable, reproducible, validated, and reflect the proposed mechanism of action. A few possible candidates for improved endpoints include steroid withdrawal and FDG-PET.

As we seek out successful clinical trials in this space, we need each to collaborate.



“Success of a clinical trial recruitment at a particular site rests solely on the clinician. Whether or not a trial is successful in recruiting at a particular site relies on whether the physician who is in the room with the patient drives that success.”

We cannot get there alone –FSR, in partnership with patients, clinicians, researchers, industry and global regulatory agencies must work together if we hope to make progress in identifying new therapies. The time is now. We must all come together to do our best to ensure clinical trials in this space are successful.

The Power of Strong Teams and Institutional Support

Panel discussion with Dr. Joseph Barney, Dr. Mehdi Mirsaeidi, Dr. Divya Patel



How do you raise awareness of clinical trials among colleagues and with patients not seen at your clinic.

In current trials, the steroid sparing endpoint has been critically important; however, at many of the large academic centers' patients are often, like Heidi, moved to second and third line therapies. This means that the potential pool of clinical trial participants from patients being seen at these academic centers may be severely reduced. How can we address these challenges:

Reach out to colleagues at your own institution

Colleagues in rheumatology, dermatology, cardiology and elsewhere within your own institution may be seeing patients who are eligible for these trials. It is critical that you reach out and inform your colleagues about trials you have underway and provide a clear path for referral.

Outreach to community-based clinical colleagues

Direct community outreach is necessary to make these trials successful. Reach out by phone, share fliers, host dinners with community clinicians that have referred patients to your care in the past, and raise awareness of clinical trials as part of conversations you have with community clinicians about patients they have referred to your care, whether that particular patient meets criteria for the trial.

“Clinical trial sites must prioritize those referrals as a sign of respect for the colleagues who refer the patients and for the patients that do not know the PIs at the study site but are still raising their hands to be a part of these pivotal trials.”

-Dr. Divya Patel

Tap into institutional resources such as community clinician liaisons

Find out if your institution has a community liaison whose job it is to build strong relationships with community-based clinicians. If so, build a strong relationship with this individual and invite them to meetings with sponsors and support group meetings to help them better understand the trials and challenges that are faced by those living with sarcoidosis.

Build trust, prioritize, and show respect for patients that don't know you or travel long distances to learn more about clinical trials

Trust is earned. Answer patients' questions. Prioritize patients interested in the trials by getting them into your clinic for evaluation as soon as possible. When candidates who are referred are not good candidates for the trial, be honest and offer your support to their community clinician.

“The patients that volunteer to be in trials should be treated like royalty... Do whatever you can to make it easier for them to be in the trial.”

– Dr. Divya Patel

Move beyond transactional relationships with the community to build trust

Far too often the first engagement with the community is when we need something, like patients to participate in research or clinical trials. However, this type of transactional engagement with the community can breed and exacerbate distrust. Before seeking anything from the community we should be reaching out with no other agenda to provide information, support, and resources.

“If patients with sarcoid looked demographically different, we would have a lot more drugs for them right now. Whether or not this is completely true, our patients do not have the options that those with other inflammatory conditions have.”

Dr. Joseph Barney

The current set of medications do not work for all patients indefinitely

As Heidi noted, for many patients, medications that work may only be effective for a short period of time. We can't afford to get to the phase when there are no more drugs left.

Since sarcoidosis is a disease of disparities, what do we need to do to reach underserved populations?

Representation matters

Your staff and research teams need to reflect the population that you wish to recruit. Staff who are diverse can bring experiences and perspectives to the trial which can help to identify and remove potential barriers to participation and improve the quality of the trial. Someone on your team should look like your patients. This has been repeatedly noted as a key factor in whether patients feel comfortable and trust their providers.

Tell all patients about clinical trials, whether they qualify or not

As noted in the *FSR Ignore No More ACT Now!* IRB-approved survey, the number one reason that patients do not participate in clinical trials is because they are not asked. By sharing with patients about clinical trials, even those trials that they are not eligible for, you open a dialogue and allow the patient to ask questions.

“By asking all patients, you are counteracting unconscious biases that may otherwise deter you from sharing clinical trial information with a patient.”

-Dr. Divya Patel

Encourage your staff to build strong relationships with the sarcoidosis community

Invite staff to reach out to sarcoidosis patients, participate in community education events, and join support group meetings. Look to engage non-traditional hospital staff who have strong relationships with the community, such as hospital chaplains, to help build trust and engage on a consistent basis with the community.

Acknowledge mistrust and concerns

Furthermore, patients who enroll in clinical trials often get better medical care than standard of care, because they are more closely monitored and seen more often.

-Dr. Joseph Barney

There is justifiable mistrust. You must acknowledge that mistrust and respect where patients are in the journey of rebuilding trust with the medical community.

Patients often fear flares with being put on a placebo. Acknowledge that some patients are motivated by altruism, but

others are seeking comfort of something like an open-label arm that will allow them access to the trial drug upon completion of the trial. Furthermore, it is vital to assure the patients that they will be closely monitored and if they have an exacerbation their providers will be there to support them and treat their exacerbation, if necessary

Understand the importance of engaging the patient's community

Patients talk to each other and support each other's medical choices. Part of trust building is talking to the patient community and allowing them to have a community of peers to discuss their fears and concerns. Talk to patients' caregivers, spouses, and loved ones. These decisions are not made in isolation. Many times patients who are on the fence in whether or not to participate in a clinical trial, make their final decision after conversations with loved ones and peers.

Seek out financial support for patients to make participation possible

Ensure that patients' travel, childcare, and out of pocket expenses are covered for patients as part of the clinical trial. Furthermore, as appropriate, seek out compensation for the patient's time and efforts.

What steps do you need to take in working with your hospital or institution to make sure your site is ready to be a part of a clinical trial?

Don't sign up to be in a trial if you don't think you can enroll

Build out your institutional infrastructure before agreeing to be a part of a trial. If you don't have the time to enroll patients, "don't sign up to participate because that paints our community in a bad light."

Make sure you have enough compensation for clinical trial participation to allow for protected time

The funding provided for clinical trials should be equivalent to how academic researchers get protected time from their institute for clinical trials. Once we establish this we can do a better job having the PIs take more responsibility for the success of a trial, as was noted by Dr. Culver above.

“The way I calculate this is to consider how many patients should be enrolled in the study. If you would like to support your own clinical researcher, you need to have approximately 9 patients per year that you are responsible for enrolling in clinical trials.”

-Dr. Mehdi Mirsaedi

Research coordinators should be substantively supported by the research coordinator

You must have a clinical coordinator who has significant time to dedicate to your study, so you are not competing against better funded research programs for their time and their dedication.

Institutes should be research-oriented

Communication with leadership about your research-directed efforts can counteract some of the pressures you may get from administrators or department chairs that pull you away from the research to focus more on billable hours. It is part of your role as a Principal Investigator (PI) to demonstrate the Return on Investment (ROI) of participating in clinical trials for the institute’s bottom line. Speak directly with administrators showing them the exact amount of money that comes from your participation in clinical trials to ensure the support.

Engage medical students, residents, and fellows

Early career professionals and junior faculty are looking to learn and grow by servicing as sub-PIs. Tap into their interest and enthusiasm to help enroll and support your clinical trial efforts.

“Today’s sub-PIs are the PI’s of the Future. Giving them opportunities now means better research in the future.”

-Dr Joseph Barney

Accept the support that sponsors offer

Sponsors often offer a menu of support services such as medical records screening, marketing and recruitment support, referral platforms.

Incentivizing the coordinators

Help the coordinators feel connected to the patients. Ensure that your coordinators feel like they are a part of the team, rather than just a cog in a wheel. Set up educational sessions with the coordinators to help them understand sarcoidosis, why it is important to study. Invite them to support groups and introduce them to patient before they start recruiting. Allow the research coordinators to engage with all the patients at the clinic, not just those who might be eligible for a trial.

Allow coordinators to build friendly relationships with patients even outside of the trial setting. This personal connection is key to tapping into their empathy and in motivating them to support the patients in whatever way possible. Emphasize the role that all team members have in making the trial successful and in improving the lives of those impacted by sarcoidosis. Your clinical research coordinators should be partners. Ask them to join you in the clinic.

Include both junior and senior level coordinators

Much like the early career clinicians and clinician researchers, coordinators are seeking out opportunities to grow. By hiring an experienced coordinator, you help junior coordinators learn and grow in their field of choice and help build buy in for sarcoidosis research.

Identifying Solutions – A Workshop Discussion

Moderators – Dr. Daniel Culver, Dr. Nisha Gilotra, Dr. Mehdi Mirsaedi

Endpoints and Eligibility

How do you approach eligibility criteria so that patients do not feel invalidated if they do not qualify

- ❖ If a patient doesn't qualify, emphasize how you intend to work with them in clinical care to find what fits them best.
- ❖ Share that though they may not fit the criteria for this trial, they may be good candidates for future trials.
- ❖ Thank them for their consideration to participate and encourage them to consider participating in the future. Share that you believe clinical trial participants are doing an invaluable service to the community.

What endpoints might be best for future trials

- ❖ Make sure that we identify a specific enough question in order to get an answer that allows for interpretability of the results.
- ❖ Make sure that the endpoints are relevant to the patients involved.
- ❖ Explore the value of FDG-PET as a mechanism for demonstrating improvement or showing slowing of progress.
- ❖ Steroid reduction may not cover all patients we want to recruit for clinical trials. This works best for those who are considering second or third line treatments. Steroid reduction may be challenging since patients do not like to be on steroids. Despite these challenges, steroids may be the best measure for this time.
- ❖ Consider composite measures – looking at different functional tests for different types of diseases.

Patient Recruitment and Retention

What can you do as study team to help identify potential candidates for trials

- ❖ Make it easy for recruitment to take place.
- ❖ This should be a team sport and should be about understanding the disease and not just about clinical trial enrollment alone.

How do we assure patients about participation in clinical trials considering their concerns about changing therapies or experiencing a flare?

- ❖ The diagnosis and treatment options can already feel overwhelming, so it is critical to meet the patients where they are.
- ❖ Start the dialogue early. Normalize clinical trials and observational trials.
- ❖ What are the benefits to the patient for enrolling in a clinical trial – closer monitoring, access to test that may not be covered by insurance, and finding new drugs for all impacted by sarcoidosis.

Institutional Infrastructure

How can you get your institution prepared to successfully active and engage in trials

- ❖ Work with the institution to help them understand how the trial can help underserved populations.
- ❖ Articulate why this study is of critical importance to advancement and science in this field.
- ❖ Need more substantive budgets that help to protect coordinator time and allow for protected time for PIs and Sub-PI's.

How to make your team most effective

- ❖ Work to have patients screened by the same coordinator for all possible trials, rather than having different coordinators screen for different trials. This is key in trust-building for the patient. They get to know the coordinator and can have candid conversations with the coordinator.
- ❖ Sponsors can help coordinators feel appreciated. Transmit these successes publicly.

Group Discussion

How do we keep clinical trial medications as part of the decision-making process in selecting therapies for a patient

- ❖ Discuss clinical trial therapies alongside other standard of care therapies in order to ensure that the patient has the full range of options for their consideration.
- ❖ Lay out the pros and cons of current therapies against the unknowns of the trial therapies for the patient to consider.
- ❖ Examine your own bias towards a particular medicine and do your best to lay out all potential options.

“Many clinicians who treat sarcoidosis patients at the community level, and even some academic clinicians, do not directly participate in clinical research and do not discuss clinical research options with their patients. Making sure that all clinicians who treat sarcoidosis patients are aware of these important observations and recommendations is critically important to expanding the number of patients who participate in clinical research.”

– Bill Gerhart, Kinevant

Conclusion

Thank you to all the participants for sharing your insights and thinking creatively about how we solve challenges in making clinical trials successful in sarcoidosis.

This paper will be circulated widely and will be utilized to help shape our discussion with the FDA as part of FSR’s upcoming Externally-Led Patient Focused Drug Development meeting with the FDA.

As Dr. Culver notes, **“Now is the most important time I have seen in my career for sarcoidosis to move forward as a field, with the support of all stakeholders. The time is now.”** Together, we can increase therapeutic options and create a brighter future for all living with sarcoidosis.

Appendix 1

Working Group Participants

Endpoints and Eligibility Working Group

Daniel Culver, DO - Moderator

Chair of the Department of Pulmonary Medicine at Cleveland Clinic - a WASOG Sarcoidosis Center of Excellence at Cleveland Clinic and Founding Member of the FSR Global Sarcoidosis Clinic Alliance, FSR Clinical Studies Network Steering Committee Member, Past Chair of the FSR Scientific Advisory Committee, Past President of WASOG, and Executive Committee Member for the Americas Association of Sarcoidosis and Other Granulomatous Disorders

Joseph Barney, MD

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Senior Research Manager, Foundation for Sarcoidosis Research

Bill Gerhart, MBA

Chief Executive Officer, Kinevant Sciences

Samsung Fung, MD

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Chief, Division of Environmental and Occupational Health Sciences, National Jewish Health Founding Member of the FSR Global Sarcoidosis Clinic Alliance, Professor of Medicine, Division of Pulmonary Sciences and Critical Care Medicine, Department of Medicine, School of Medicine, Department of Environmental/Occupational Health, Colorado School of Public Health, University of Colorado Denver

Mary McGowan, MHRM

CEO, Foundation for Sarcoidosis Research

Brandon Moss, MD

Director, Neurosarcoidosis Clinic at Cleveland Clinic and Assistant Professor of Neurology, Cleveland Clinic Lerner College of Medicine – Founding Member of the FSR Global Sarcoidosis Clinic Alliance

Varsha Taskar, MD, MPH

Professor of Medicine, Division of Pulmonary, Critical Care and Sleep Medicine at Wellstar MCG – FSR
Global Sarcoidosis Clinic Alliance Member

Patient Recruitment and Retention

Nisha Gilotra, MD - Moderator

Director, Cardiac Sarcoidosis Program, Associate Professor of Medicine, Johns Hopkins Medicine

Alejandro Bohorquez

Associate, Kinevant Sciences

Yvette Goldsborough

Clinical Research Program Specialist, Johns Hopkins Medicine

Heidi Junk

FSR Board Member, FSR Patient Advocate, FSR Patient Navigator, and woman living with pulmonary and neurosarcoidosis

Tim Legenzoff

Research Manager, Foundation for Sarcoidosis Research

Divya Patel, DO

Director, Clinical Development and Medical Affairs (IPF/ILD) at Boehringer Ingelheim and is an Adjunct Clinical Associate Professor of Pulmonary and Critical Care Medicine at the University of Florida, a founding member of the FSR Global Sarcoidosis Clinic Alliance

Clara Restrepo, MD

Associate Professor, Director, Sleep Laboratory, Division of Environmental & Occupational Health Services, Department of Medicine, National Jewish Health – Founding Member of the FSR Global Sarcoidosis Clinic Alliance

Rayne Rodgers, MPH

Senior Director, Head of Patient Advocacy, Kinevant Sciences

Noopur Singh

VP of Marketing & Patient Affairs at Xentria, Inc.

Institutional Infrastructure

Mehdi Mirsaeidi MD, MPH – Moderator

Professor of Medicine, Chief, Division of Pulmonary, Critical Care and Sleep, Director of ILD and Sarcoidosis Program, College of Medicine-Jacksonville University of Florida – Founding Member of the FSR Global Sarcoidosis Clinic Alliance

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Vice President, Deutsche Sarkoidose-Vereinigung e.V.

Tricha Shivas, MBe

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