

Dedicated to Providing Information and Support Related to the Causes, Symptoms, Diagnosis and Treatment of Myocarditis and Sudden Death

MYOCARDITIS
FOUNDATION



EVENT

Myocarditis Foundation Golf Outing 2023, Paramus, New Jersey



On Monday, August 14th, the Myocarditis Foundation held its **16th Annual Golf Outing / Fundraiser** at the beautiful Arcola Country Club, overlooking the New York City skyline, from Paramus, New Jersey.

It was, once again, a sellout crowd with most attendees being key, repeat supporters of our mission. We want to thank the many corporate sponsors of the event, especially our lead sponsors Morgan Stanley, Town Title, Enight Merchant Services, HomeWell Care Services, Cardiol Rx, Kiniksa Pharmaceuticals and Jim and Candace Moose.

We would not have been able to have such a successful event without their support!

The success of the outing allows us to continue our mission, support our research grants and provide the help and care to those affected by the disease.

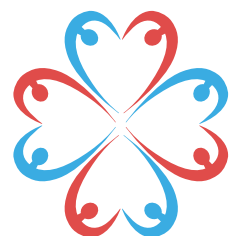
Also, during the golf outing, the Myocarditis Foundation held an intimate Family Meeting where a few families interacted with the Executive Director, Genevieve Rumore, Dr. Leslie Cooper, Candace Moose, (co-founders), Board member Francine Andrea and our Patient Advocate,

Giustina Schiano. The support to these family members in need was very individual and personal.

It was extremely gratifying to report at both events, after many years of raising awareness on Myocarditis, that there are a number of current clinical trials specific to various aspects of Myocarditis.

A huge thank you to all those who attended and or supported our event.

We look forward to our August 12, 2024, event! Hope to see you there!



Myocarditis Foundation 2023 Family Support Meeting, October 6th and 7th, Cleveland, Ohio



At least once a year the Myocarditis Foundation holds an In-Person Family Meeting where we all get together at a hotel, often near where the Heart Failure Society of America is having their annual meeting. We invite new Patients and Families, along with our previous attendees, Cardiologists and Researchers, who specialize in Myocarditis and Pericarditis, to share our stories and learn that they are not alone in their journey and learn the latest developments in these fields.

It was a wonderful success helping new families better understand the Myocarditis Journey that they are on as survivors or having lost loved

ones. The new attendees to our "Family" truly had no idea what to expect despite our explanation of what it involves. The comments on our evaluations that the attendees handed in at the end of the meeting proved that we accomplished what we had hoped for...to help others understand more about the disease and what the Myocarditis Foundation does to bring others together and provide them with resources moving forward.

We had attendees from 15 different states as well as from Canada, and the U.K. in attendance.

Last year, we started to invite representatives from various

Medical Device and Pharmaceutical Companies, that support medications, treatments, and mechanical support for these diseases, or are working on medications, treatments, and diagnostics of the diseases. We had feedback from them that they never realized the impact that these diseases have on patients and their families and were thankful to be invited to learn more about the Myocarditis Foundation and what it does for those affected.

In addition, the Pharmaceutical Companies who are manufacturing medications that deal with the long-term complication of Heart Failure see the patients first-hand and better understand the importance of their work.

Supporters of our Family Meeting included: D&I Printing; 4 Imprint; Donna D'Orazio Accounting Services; MJM Global Insurance Brokerage Group; as well as two major supporters

which are Pharmaceutical Companies, Kiniksa Pharmaceuticals and Cardiol Therapeutics, that are working on medications to treat Pericarditis and Myocarditis. They have either developed or are having Clinical Trials for a medication for Recurrent Pericarditis, Acute Myocarditis, and Dilated Cardiomyopathy which can be a complication of these diseases.

We are looking at the possibility of doing our In-Person Family Meeting earlier next year and not at the same time as the Heart Failure Society of America's (HFSA) meeting. We are in the early planning stages but are looking at making it more:

"Family Oriented", and not a full day of meetings but possibly breaking it up to spend time with your families over a few days. Look for more information to come!

EDUCATION

Seasoned Specialist's Report at the 2023 Family Meeting:



Dr. Renata Engler, a Retired Army Colonel and Immunology Specialist affiliated with Walter Reed Hospital, Bethesda, Maryland, joined us via Zoom to speak about COVID Vaccination and Long COVID Syndrome. She shared that when the immune system gets turned on to fight the virus that is attacking the body,

sometimes it doesn't cool down when it should. This is what causes recurrent inflammation and "Long-COVID Syndrome." She has generously offered us to share her email with our families and welcomes your questions related to Vaccines.

Renata.Engler@gmail.com



Dr. Leslie Cooper, Chair of the Cardiovascular Department of

the Mayo Clinic, Jacksonville, Florida location, our Co-Founder and Medical Director, spoke on the founding of the Myocarditis Foundation. Together with the help of Candace Moose (Co-Founder) and survivor of Giant Cell Myocarditis (GCM) and a heart transplant recipient, they founded the Myocarditis Foundation in 2005.

Dr. Cooper spoke about a study on "Anxiety and Depression in Myocarditis", that the Myocarditis Foundation funded. There are over 200 patients and caregivers enrolled, but they are still in need of about 25 people not affiliated with anyone

dealing with myocarditis to enroll as "controls" for the study. If you can help with this, please email Daniel Smith at Mayo Clinic:

Smith.Daniel3@mayo.edu



Dr. Jack Price, a Pediatric Cardiologist at Texas Children's Hospital (TCH), Board Member, and Pediatric Medical Director for the Myocarditis Foundation

provided us with updates on three studies on Pediatric Myocarditis.

There is a study being conducted on the Global Burden of Myocarditis in Children, which is utilizing information obtained in 2019 and will be completed in 2035. Sadly, research takes many years to evaluate and ascertain the answers it sets out to obtain. There are 11,755 children with myocarditis and cardiomyopathy world-wide. While the rates are on the rise, mortality is decreasing. Could this be because more is known about earlier diagnosing of the disease and improved treatment options?

Dr. Price also spoke about the newer temporary mechanical assist devices that are being used more frequently than ECMO. ECMO is still being used when there is need for pulmonary (lung) support, as these newer temporary mechanical assist devices require working lungs to be utilized. These pumps take the stress and strain off the heart function allowing the heart to heal. It is not as invasive as performing ECMO assistance. The smaller pumps are threaded into the heart through the arm or the groin and do not require an operating room suite to perform it.

In a study that he referenced, 84% of children hospitalized who needed mechanical support to offload the work of the heart affected by severe myocarditis survived when these assistive devices were utilized. Only 61% of those hospitalized with severe myocarditis, who were not given the assistive devices survived. Pumps are being utilized more frequently.

At TCH, 20 years ago only one child was assisted with a mechanical pump.

In 2022, 16 children benefited from mechanical support of those hospitalized with severe myocarditis at TCH.

Another Study that Dr. Price referenced, was on Cardiogenic Shock (when the heart is not pumping well) in children. Information on adults suffering from Cardiogenic Shock is far ahead in knowledge and treatment, but those studying pediatric Cardiogenic Shock are starting to learn more. In a study of 800 children with Heart Failure, 26% had Cardiogenic Shock. The trend was more towards females. 24% of these heart failure patients had myocarditis. They are finding that children do not

always present with fluid in their lungs or edema of the extremities like adults do but do present with elevated liver enzymes and decreased kidney function. They have decreased blood pressure, cool extremities, and increased lactic acid in their bloodstream on blood testing.

There are hospitals that are now putting together "Shock Teams", where when there is a need, much like when they call a "Code Blue" for a cardiac arrest, a team of specialists respond to care for the patient immediately.



Dr. Wilson Tang, Cardiologist and Research Director of Heart Failure and Cardiac Transplantation Medicine at Cleveland Clinic, as well as a member of the Myocarditis Foundation Medical Advisory Board, spoke about several important needed developments in the diagnosing and treating of Myocarditis patients.

He made a very impactful statement in his talk: What can we do to recognize patients earlier before the "roof is on fire"?

He spoke about studies that are being conducted at Washington University as well as at University of Pennsylvania.

One area that is now being studied is why do some people develop myocarditis from a virus and others do not? Is it "bad luck" or is there another reason like a gene that causes it? They are looking at gene studies to see if there is a gene that have an inherited vulnerability to developing myocarditis.

A diagnostic and treatment regime is a must to be developed so that it is standardized no matter where a person goes to be evaluated. Right now, we have multiple hospitals doing smaller studies, but larger numbers of patients are needed to do the studies. We need a large amount of funding by the National Institute of Health, which they have not done so thus far, to better study myocarditis.

ANNOUNCEMENT

Dr. Javid Moslehi, MD Appointed to Medical Advisory Board



Dr. Javid Moslehi, MD, has recently been appointed to the

Myocarditis Foundation's Medical Advisory Board. He has a very impressive CV and was recently appointed as the Director of Myocarditis at the University of California, San Francisco (UCSF) School of Medicine. He also is the Section Chief for the Cardio-Oncology & Immunology Department at UCSF as well.

He was a mentor for our 2019 Fellowship Grant Recipient while working at Vanderbilt University Medical Center.

Dr. Moslehi was awarded the Sarnoff Scholar Award, in 1999, which is a very prestigious award that is presented to Cardiac Fellows who are committed to

pursuing a career in cardiovascular research.

Welcome to Dr. Javid Moslehi, as he joins the Myocarditis Foundation's prestigious International Medical Advisory Board!

Clinical Trials, what They Are and Why They Are So Important ...



Clinical trials are research studies that test a medical, surgical, or behavioral intervention in people. These trials are the primary way that researchers determine if a new form of treatment or prevention, such as a new drug, diet, or medical device, is safe and effective in people.

There are 4 Phases of Clinical Trials:

Phase I Clinical Trial:

Doctors do a phase I clinical trial to learn if a new drug, treatment, or treatment combination is safe for people. They may have already tested it in laboratory animals. These trials usually last several months to a year. They usually have 10 – 30 volunteers. Doctors collect information on the dose or treatment, when and how often you take it, any side effects, or problems, and how the treatment affects you or side effects.

Phase II Clinical Trial:

A phase II clinical trial tells doctors more about how safe the treatment is and how well it works. A Phase II clinical trial lasts about 2 years. Volunteers sometimes receive different treatments. For example, a phase II trial could have 2 groups.

- Group 1 – People who receive the usual treatment for the condition. This is also called the standard treatment. It is the best treatment known.
- Group 2 – People who receive the usual treatment plus the new treatment doctors are studying.

Or a phase II clinical trial could have 3 groups. Volunteers in each group get a different dose of the treatment doctors are studying.

If the phase II clinical trial shows the treatment works and is as safe as the regular treatment, doctors can do a phase III trial.

Doctors use a computer program to put volunteers into different groups. The computer does this at random, which means by chance. Each volunteer has an equal chance of going in any of the groups. The name for this process is “randomization.”

Using a computer to put volunteers in groups keeps the research staff from possibly changing the clinical trial results. They might do this if they chose who went in which group. For example, they might

think a certain volunteer would benefit from the new treatment. So, they might put that person in the new-treatment group. But this could change the clinical trial results. Randomization helps avoid this. It is very important to use randomization when a clinical trial compares 2 treatments or more.

Phase III Clinical Trial:

A phase III clinical trial tests a treatment that worked well for volunteers in a phase II clinical trial. Doctors use phase III to compare the new treatment with the standard treatment. They want to know if the new treatment is better, has fewer side effects, or both. So, they put volunteers in different groups. The volunteers in each group get a different treatment.

Phase III clinical trials can take many years. They may have several thousand volunteers. These must include men, women, and people of different ages and ethnic groups, if possible. This helps doctors learn how the treatment works in different people.

If a phase III clinical trial shows the treatment works well, doctors might begin using it with people outside the clinical trial. For example, if they learn that a certain amount of exercise lowers your cancer risk, they publish a report. This shares the information with other doctors. If the researchers or sponsor learn a new medicine is safe and effective, they can ask the government to approve it for people to use. In the United States, they ask the Food and Drug Administration (FDA). The FDA looks at the results of the clinical trial’s phases. They approve the treatment if the results meet their standards.

Phase IV Clinical Trial:

Doctors can prescribe a drug for their patients after the FDA approves it. But the FDA may require the sponsor to keep studying that approved treatment. In these clinical trials, doctors may check if the treatment benefits people as much as it did earlier. They also look for more possible side effects. These clinical trials are called phase IV clinical trials.

In a Phase IV clinical trial, doctors might study the drug or treatment in different doses, or with other drugs or treatments. Or they might study how it works if people take it at different times. They might study it in different people than earlier clinical trials did. For example, they might study how well it works for children or older adults. Doctors can also study how well a drug or treatment works overtime.

Drug makers may do phase IV clinical trials even if the FDA does not ask them to. They might do this to get FDA approval to use the drug in a new way.

Phase IV clinical trials can also check the safety of drugs or treatments being used now. They do this to make sure drug makers report any new or serious side effects. The FDA may take away a drug’s approval if new research shows it is not as safe or effective as earlier testing showed. Doctors cannot prescribe it any longer if this happens.

Do I need to be in all the phases of a clinical trial?

No. You can join any phase of a clinical trial if you qualify to join. For example, you may join a phase II clinical trial whether you were in phase I, or not.

You always have a choice to be in the clinical trial, and you may leave at any time.

There are two Pharmaceutical Companies that are working on medications to treat Pericarditis and Myocarditis. They have either developed or are having Clinical Trials for a medication for Recurrent Pericarditis, Acute Myocarditis, and Dilated Cardiomyopathy which can be a complication of these diseases.



Dr. Mark Bechter, Vice-President of Operations & Patient Advocacy for Kiniksa Pharmaceuticals, traveled from the United Kingdom for our Family Meeting specifically to learn more about the Myocarditis Foundation and what we do for our patients and families. Kiniksa's Mission is to develop safe, effective, and transformative treatment options for patients with debilitating diseases. Two such diseases are Myocarditis and Pericarditis. Pericarditis can be very limiting if a person has recurrent flareups causing debilitating pain. Kiniksa has recently developed a medication to treat recurrent Pericarditis.

Arcalyst (rilonacept) is the first and only FDA-approved treatment, at present, to treat recurrent Pericarditis and reduce the risk of flares in people 12 years and older.

Dr. Bechter shared with us that in 2021, they started a registry to follow patients to see how they do over a period of time. Many of the patients have agreed to do a long-term treatment study on the effects of rilonacept. With it being a new drug, there is nothing to help the doctors prescribing it to know how long a person should be given the treatment for. This study will help them better understand that. Dr. Bechter expressed that it is critical to collaborate with other doctors on the treatment of recurrent pericarditis. There are currently 20 sites in the United States that are recruiting patients with pericarditis for this study.

To get to our listing of Clinical Trials on our website:
www.myocarditisfoundation.org/clinical-trials/

It will tell you which studies are recruiting, and you can click on them to learn more information.

If for some reason, you are not near one of the enrolling facilities, please contact *TKL Research* where they will enroll you at a decentralized site.

If you have any further questions, please contact us at the Myocarditis Foundation and we will try to help.



Dr. Andrew Hamer, Chief Medical Officer and head of Research and Development for Cardiol Therapeutics, based in Ontario, Canada. Dr. Hamer participated in our Family Meeting last year and returned to share updated information on their Clinical Trials and learn more about our Foundation as well. Dr. Hamer was joined by Kelly Narine, Director of Medical Affairs at Cardiol Therapeutics. Cardiol Therapeutics is a clinical-stage, life sciences company which focuses on the research and development of anti-fibrotic and anti-inflammatory therapies for the treatment of cardiovascular disease. Its lead product is CardiolRx, which is in a Phase II Trial (ARCHER Trial), for the treatment of Acute Myocarditis.

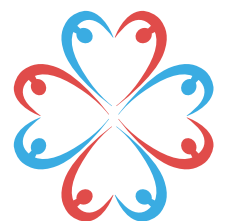
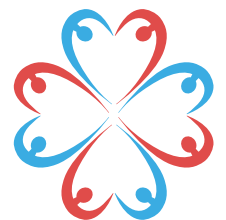
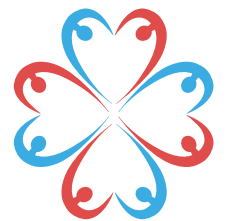
Dr. Hamer spoke about how difficult it is to get this trial awareness out to cardiologists in the U.S., as most patients who get initially seen do not go to large diagnostic centers where they are recruiting for this and other studies.

Dr. Hamer encourages patients diagnosed with myocarditis to contact the site that is enrolling patients in this study, which is closest to them, and plan to have travel reimbursed if needed. He shared that the pre-clinical data in this Myocarditis study is very good so far in decreasing the scarring by treatment with this medication.

Cardiol Therapeutics is also recruiting patients who are suffering with recurrent Pericarditis. **Please go to our website to access information about these Clinical Trials and others.**

If you are having any problems enrolling in the Cardiol Rx trial, please contact:

Andrea B Parker, MSc, PhD
+1 289.910.0862
andrea.parker@cardiolrx.com



FUNDRAISERS

Sarah Knight Memorial Golf Outing, Marion, Iowa June 2023



Susan and Greg Knight lost their adult daughter, Sarah, suddenly to Viral Myocarditis in September 2011. That changed their lives forever.

The word myocarditis struck fear and sadness in their hearts, and they decided to do something to prevent others from suffering what they had gone through.

Sarah's favorite quote by Eleanor Roosevelt, that gave her family the courage to try to do this was: "What would you do if you knew you could not fail?" It has inspired tens of millions to face their fears and dare to follow their hearts, including the Knight Family of Marion, Iowa.

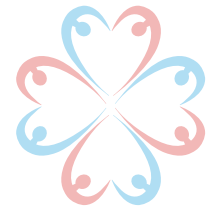
Eleven years ago in 2012, the Knight Family started the Sarah Knight Memorial Golf Tournament in her memory. The tournament would be in support of Fellowship Grants in Myocarditis to the Myocarditis Foundation and scholarships to Bi-Lingual Elementary Education majors at Western Illinois University, where she received her teaching degree.

Since then, with the support of their family, friends, business associates, etc. they have raised over \$300,000 for these Foundations. Dr. Leslie Cooper was the Guest Speaker at this year's event.

The Knight Family has supported 3 Research Grants for Myocarditis Research, which they believe is the key to finding the answers to fighting this disease. They are halfway to their 4th Research Grant with this year's event.

The Myocarditis Foundation cannot thank the Knight Family enough for all their hard work and continued support!

Mark your calendar for next year's event: Jun 7, 2024, in Marion, Iowa.



FUNDRAISERS

Birthday Party for Banner, Marriottsville, Maryland May 6, 2023



Kara and Forrest Watson, parents of myocarditis victim Banner Watson (2011-2018), held a party for him on what would have been his 12th birthday. It was both a birthday party and a myocarditis fundraiser. With about 120 people in a large backyard setting, they brought together crowds of kids and families— his

siblings and cousins, former friends, and even new kids who never knew him – for ziplining, trampoline jumping, yard games, and a dinner buffet.

With the roasted chicken, ice cream cones, and the venue all provided by local sponsors and friends, guests were asked to read the story boards of kids who died of myocarditis, including Banner, and donate

to the Myocarditis Foundation. They raised nearly \$3,000 in Banner's memory.

His parents would love most of all to see Banner as a 12-year-old, mingling with his charisma amidst the crowd or slinging down the zipline with his radiant smile. Or raising his brother Brave (whom he never met) up in the air as everyone sings the final word of the

"Star-Spangled Banner." Or kissing his mom's belly as he awaits his newest baby sister. But they are glad Banner is still remembered and celebrated and that some good is coming from grief. His parents wholeheartedly support the work of the MF to bring research, education, and awareness to a world where fewer kids are lost to the sudden onset of this awful condition.

Myocarditis Research



One of our Fellowship Grant Recipients, **Dr. Tahir Kafil**, who was awarded a Myocarditis Foundation Fellowship Grant in 2021 to study “COVID-19 Vaccine Induced Inflammatory Heart Disease” in Canada, spoke about his research and findings. His talk was entitled, “Lessons from the Myocarditis Clinic” about his time in Ottawa, where he had helped establish the Post-Vaccine Myopericarditis Clinic. His research work went on to help develop a pan-Canadian study called MYCOVACC which won 1.6 million from the Public Health Agency of Canada to study the clinical and functional outcomes of adults and children who experienced Myocarditis and/or pericarditis after receiving an mRNA COVID-19 vaccination or after COVID-19 infection.



Dr. Shahnawaz Amdani, a Pediatric Heart Failure and Transplant Cardiologist at the Cleveland Clinic Children’s Hospital, was interested in learning more about the Myocarditis Foundation and offered to speak. He spoke on “Myocarditis after COVID Vaccine in patients with a prior history of Myocarditis.” What they found in the study at the Cleveland Clinic, the risk for recurrence after getting the vaccine is very low. In contrast, the risk of developing myocarditis from COVID-19 is significantly higher.



Dr. Katelyn Bruno, PhD, Myocarditis Researcher at the University of Florida, College of

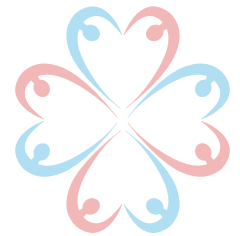
Medicine, and Secretary to our Medical Advisory Board, joined us to share her recent research on the three areas that she is looking at with relation to Myocarditis.

Before Dr. Bruno’s study on Pediatric Viral Myocarditis, there were no mouse models, which basically are what are studied before human models of the disease. Dr. Bruno utilized the knowledge that she had gained from their adult mouse model of coxsackie virus B3 (CVB3) myocarditis to create a pediatric CVB3 myocarditis model the better understand the development of myocarditis in children.

Dr. Bruno shared that the successful development of a pediatric viral myocarditis model will significantly impact the myocarditis field by allowing the ability to assess differences between pediatric and adult populations and develop targeted diagnostics and treatments. Additionally, it could help increase awareness and understanding of the clinical manifestations of myocarditis in children.

Additionally, she spoke about a new diagnostic test that is being studied to detect myocarditis and dilated cardiomyopathy. The test is called a “Magnetocardiogram”, is very efficient, nearly instant – only takes 90 seconds of scan time and is ideal for vulnerable populations such as pregnant women, children, and the elderly as well as those with severe renal disease, heart failure and cancer. The results are standardized and easy to interpret. This is currently being studied in several cardiovascular diseases.

And finally, Dr. Bruno shared “new hope” for healing. There is a product that is secreted from stem cells called secretome, that they are looking at for myocarditis treatment, and potentially protecting cells from developing Myocarditis and Dilated Cardiomyopathy (DCM).



FUNDRAISERS

John Phillip Foundation Golf Outing, September 16, 2023, Acushnet, Mass



Unfortunately, the weather did not cooperate, and the golf portion of their event is rescheduled for June 2024, in addition to their regularly scheduled event in the Fall of 2024. The dinner portion was

wonderful, and Joe Rumore spoke on behalf of the Myocarditis Foundation and presented them with a plaque in honor of the Fellowship Grant that was named for John Phillip Mello and was awarded in December 2022 to Dr. Jennifer Myers at the University of Oklahoma. The Foundation is currently working on their second Fellowship Grant in John’s memory.

FUNDRAISERS

Austin Vonckx Fundraiser, August 20, 2023, Wesley Chapel, Florida



Brenda Vonckx, whose son Austin died of viral myocarditis in 2014, hosted her annual fundraiser in Austin’s memory on August 20 at Wesley Chapel Board & Brush in Tampa. Brenda and 23 of her friends spent the afternoon crafting

personalized wood projects while enjoying food, wine, and a room full of camaraderie and good fun. Between raffles and the studio’s contribution, a total of \$1,552.40 was raised for the Myocarditis Foundation. Brenda has raised more than \$10,000 for the foundation since starting her small but mighty fundraisers in 2015 and looks forward to hosting many more!

MYOCARDITIS FOUNDATION

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JAVID MOSLEHI, MD

Director of Myocarditis at the University of California, San Francisco (UCSF) School of Medicine; Section Chief for Cardio-Oncology & Immunology Dept. at UCSF

Secretary to our Medical Advisory Board

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