THE OUTLOOK

THE MYOSITIS ASSOCIATION®

2024 TMA Patient Ambassador Awardee Karen Alexander

This themed issue on cell therapy sponsored by Bristol Myers Squibb, Cabaletta Bio, and Novartis

WINTER 2024
Quarterly Magazine

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THE OUTLOOK

A quarterly publication of The Myositis Association

This issue of The Outlook features several pages of content about cell therapy, an exciting new area in myositis science.

TMA's mission is to improve the lives of persons affected by myositis, fund innovative research, and increase myositis awareness and advocacy.

TMA's vision is a world without myositis.

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Trailblazing supermodel Karen Alexander receives TMA Patient Ambassador Award

Karen Alexander with Kathy Perez

Every year, TMA presents our Patient Ambassador Award to an individual or group who has demonstrated extraordinary effort and success raising awareness of myositis diseases among the public. In 2024, it was our great honor to bestow this award on Karen Alexander.

Kathy Perez, head of Global Patient Advocacy and Policy at argenx, who sponsored the evening, introduced Karen, a groundbreaking Black fashion supermodel who was diagnosed with dermatomyositis in 2016. Professionally, she is known for her extensive work with distinguished publications, designers, and photographers over an extensive career spanning four decades. Karen has been featured in and on the covers of many major magazines. In 1986, Karen was the first Black model to appear on the cover of *Elle*. The following year she was featured in the *Sports Illustrated* swimsuit issue. Karen has starred in countless advertising campaigns for major fashion and beauty brands and walked the runway for some of the world's most well-known designers, and she continues to expand the rich legacy of Black fashion models.

Behind the scenes, though, it's Karen's three remarkable daughters, Zora, Ella, and Audrey Rose who keep her going. They joined her for the awards presentation on September 6 along with her mother and siblings. Karen's determination to live her best life is fueled by her family and friends—her people. In her DM treatments, she is laser-focused on enhancing her health so that one day she can meet her grandkids.

Beyond her work in fashion, Karen has been a dedicated hospice volunteer for more than three decades, supporting patients through their end-of-life care. Since her diagnosis, Karen has used her platform to raise awareness of and foster community around myositis diseases.

"It's hard being human, and it's really hard to be a human with a challenging, incurable condition like myositis," Karen says. "Since my diagnosis, I have turned to the TMA community more times than I can count. It is a great honor to receive TMA's Heroes in the Fight Patient Ambassador Award. But this award is just the beginning of my work with TMA. Together I believe that we women of color can help to change the face of this disease."

TMA is proud to recognize Karen as a true example of the resilience of the myositis community. We are grateful for her efforts to increase awareness of these rare diseases. Learn more on the **TMA blog**.

Celebrating our connection

TMA's 2024 International Annual Patient Conference in Baltimore, Maryland in September brought together more than 400 members of the myositis community for a weekend of connecting, learning, and celebrating. Here are some of the highlights of this amazing family reunion.

Photos courtesy of Laurie Boyer, Paula Eichenbrenner, Chip Galloway, Barbara Gomez/District Pixel Photography, Linda Kobert, Gabriela Lothrop, Michael Peck, and Julie Schumacher.

Excursion to Johns Hopkins Myositis Center

TMA's Women of Color Affinity Group

Canadian attendees and Myositis Canada members

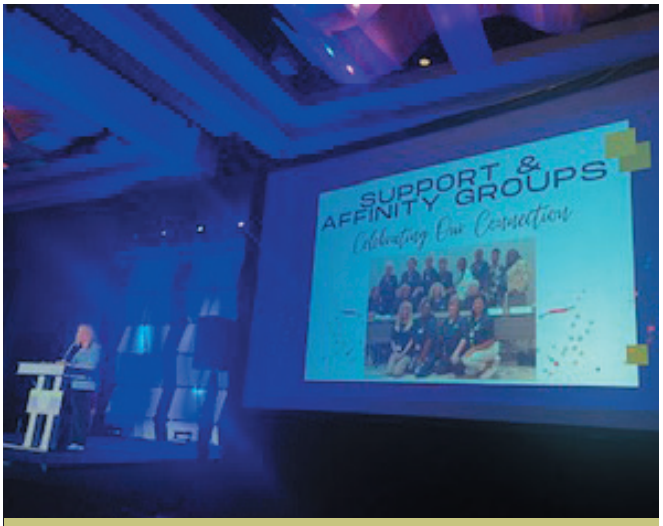
Hanging out with the Baltimore Oriole

Laurie, Karen Alexander, Kathy Perez

Ingrid Lundberg presents diagnostic criteria

TMA team

Ask me anything about PT



Celebrating TMA support and affinity groups

Heroes in Research awardee Dr. Tom Lloyd and his wife

Martha Arnold and Laurie Boyer

Heroes in the Fight awardees

CAR T cell therapy on the horizon for myositis

By Bridget Flavin, PharmD

Chimeric antigen receptor T cell therapy, or CAR T cell therapy, is an innovative type of treatment that uses a person's own immune system cells to achieve its effect. The first CAR T cell therapy became available in 2017 for use in blood cancers. New research, however, indicates that CAR T cell therapy can also be used to effectively treat B cell driven autoimmune conditions like myositis.

Steps in treatment using CAR T cell therapy

CAR T cell therapy is not yet approved for the treatment of myositis and therefore can only be accessed through a clinical trial. To participate in one of these trials, individuals must first undergo an eligibility screening to determine whether they meet the inclusion criteria. This may require tests and exams to be performed or blood to be drawn.

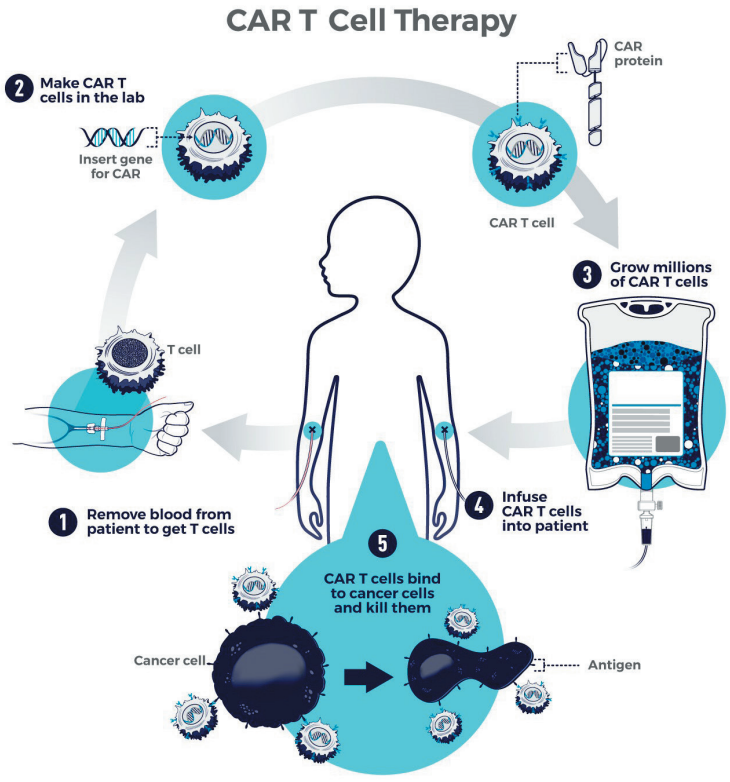
Once entered in a trial, the next step is to collect the immune system T cells. This is done using apheresis, a process resembling blood donation. The person's blood is withdrawn and spun in a centrifuge to separate the T cells, then the remaining blood is returned to the body. The apheresis process usually takes about two to three hours to complete.

The collected T cells are sent to a specialized lab to be engineered into chimeric T cells. The new chimeric T cells are then multiplied and purified and, finally, undergo testing and quality control before being returned to the infusion center where they will be infused back into the patient. Overall, this process can take several weeks to complete.

In preparation for receiving their CAR T cell therapy infusion, individuals may be required to discontinue most of their immunosuppressive medications. It's possible that some treatments, such as prednisone and immune globulin therapy, may still be taken.

They will then receive a short course of the medications fludarabine and cyclophosphamide a few days before the infusion. This process, known as lymphodepleting or conditioning chemotherapy, is done to remove all of the T cells currently in the body so the new CAR T cells can reset the immune system.

The dose of CAR T cell therapy is given in one infusion that generally takes 30 minutes to an hour. Once the infusion is complete, the new T cells will multiply and bind to their target B cells circulating in the blood.



Source: National Cancer Institute

How CAR T cell therapy works in myositis

Immune system B cells are the source of the autoantibodies responsible for myositis. Depleting these B cells can lessen disease activity and, if they are depleted deeply enough, new B cells (naïve B cells) will emerge that no longer produce myositis autoantibodies. This adjustment to the immune system can be accomplished with CAR T cell therapy, which works by directing a person's own immune system T cells to specific markers (antigens) on their B cells. When the reworked T cells recognize these markers, they bind those problematic B cells and destroy them.

The binding and activation of T cells occurs naturally in the immune system, but directing them to specific cell markers for the purpose of treatment is difficult. With CAR T cell therapy this is overcome by combining T cells and antibodies, because antibodies are more easily directed. This engineering is done in a lab after a person's T cells are collected. The result is a chimeric T cell, which is where CAR T cell therapy gets its name.

What happens after treatment with CAR T cell therapy

Individuals will need to be monitored closely for several weeks or months to detect signs of severe, life threatening, or fatal complications. The most serious risks that may occur during this time are related to excessive release of immune system molecules called cytokines.

The release of cytokines happens naturally in the body all the time, but a large release that may occur with CAR T cell therapy can lead to complications. These can include cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS). These complications can cause effects in the nervous system such as seizures, blood flow problems like severely low blood pressure, and dysfunction of some organs such as the liver or lungs.

Risk of infection is also higher following treatment with CAR T cell therapy, because the person's previously developed immunity will be diminished by the conditioning therapy. Individuals must be closely monitored for signs of infection and may need to take precautions to avoid contracting colds, flu, or other infections. Medications, which may include antibiotics, antivirals, or antifungals, will likely need to be taken for several weeks or months as a precaution.

Ongoing monitoring for several months or years is also necessary following treatment with CAR T cell therapy. This monitoring will determine how well the treatment is working and that B cells are returning to normal levels. If certain B cells remain too low, some immunizations may need to be repeated.

There may also be negative effects from the treatment that take longer to develop like T cell cancers, such as lymphoma, but what all these effects are and what makes them happen is not well understood. As more research is conducted in those with autoimmune conditions, this understanding will continue to improve.

"What we're trying to do is give the patient back their immune system that they had before they got autoimmune disease."

— Dr. David Fiorentino

"The horizon of cell therapy in myositis extends beyond autologous CAR-T cell therapy and DNA-based CAR-T cells. Allogenic therapy, RNA-based CAR-T cells, and CAR-NK therapy are three exciting pathways, which may lead to more immediate treatment for patients."

— Dr. Tahseen Mozaffar

Cell therapy in myositis: A glossary of terms

Acquired immunity – Immunity that develops when the immune system responds to a foreign substance or microorganism.

Antibody – A protein produced by the body that helps fight infections, toxins, or other disease-causing substance and are found in the blood. They are made by B lymphocytes. Each antibody binds to a specific part of a protein or antigen.

Antigen – A protein or other molecule that causes an immune response.

Apheresis – A procedure in which certain blood cells are removed from the body and used for medical treatment. In CAR T cell therapy, white blood cells called T cells are removed and modified to enable them to target disease-causing cells.

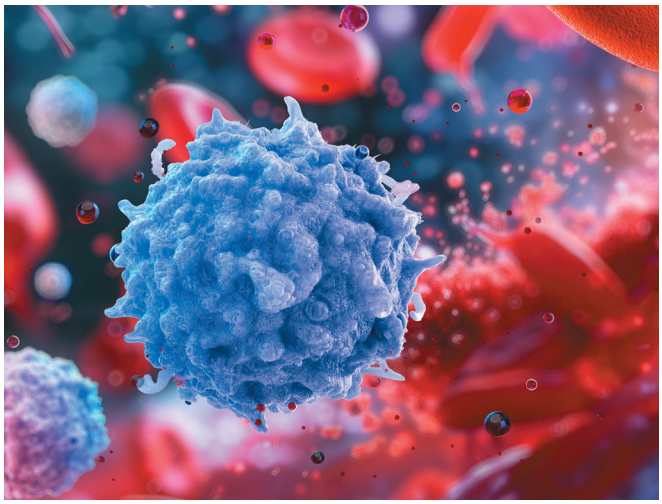
Autoantibody – An antibody produced by the immune system that attack an individual's own proteins as if they were foreign substances. Autoimmune diseases like myositis are associated with autoantibodies.

Autoimmune disease – A condition in which the immune system mistakenly targets and attacks healthy, functioning parts of the body as if they were foreign organisms.

Autologous cell therapy – Treatment that uses cells collected from the individual's own body. These cells are removed, modified outside the body, and returned to the body to target disease-causing cells. Using someone's own cells makes it less likely to cause a harmful immune response compared to the use of donor cells. It may be helpful to remember that 'auto' means self.

Allogeneic cell therapy – Treatment that uses donor cells from someone other than the patient. Like autologous cell therapy, these cells are modified to target disease-causing cells. It may be helpful to remember that 'allo' means other.

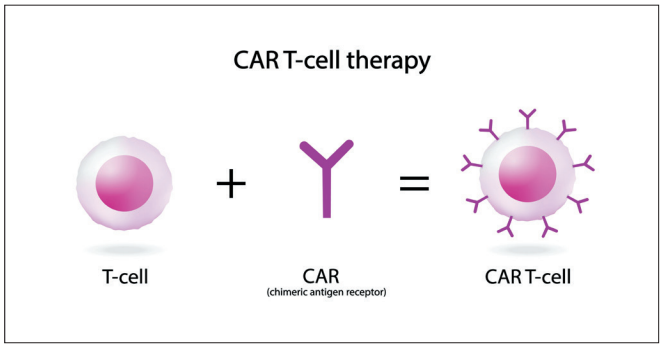
B cell (B lymphocyte) – A type of white blood cell involved in the acquired immune response. B cells are produced in the blood in response to a specific disease-causing substance such as a virus, bacteria, or toxin (antigen) and are responsible for producing antibodies that rid the body of these disease-causing substances.



Cell therapy – The transfer of a specific type or types of human cells into a person to induce a therapeutic response. Different types of cells can be modified in specific ways to treat different conditions. Some of these include stem cells, nerve cells, and pancreatic islet cells. Current cell therapy for myositis involves immune cells.

CAR NK (natural killer) cell therapy – Natural killer (NK) cells that are modified to incorporate chimeric antigen receptors (CAR) that will quickly target and destroy disease-causing cells. NK cells naturally disappear in about two weeks, so any potential side effects from CAR-NK cell therapy can possibly resolve without treatment. This also suggests, however, that this therapy might need to be repeated to maintain remission.

CAR T cell therapy – A treatment that modifies a type of immune cell called T cells to recognize and destroy certain cells (B cells – another type of immune cell) involved in autoimmune diseases like myositis.



Chimeric autoantibody receptor (CAAR) therapy – CAR cells that target specific autoantibodies on B cells to treat those whose autoimmune disease is caused by that autoantibody. This is still in the very early stages of development.

Cytokine – A type of protein made by certain immune and non-immune cells and that has an effect on the immune system. Some cytokines stimulate the immune system, others slow it down.

Disease activity – Symptoms currently and actively being experienced, such as muscle weakness and skin rash.

DNA-based CAR T cells – CAR T cells that are created by inserting a DNA sequence into the cells' structure that permanently changes the cells. This form of CAR T cell therapy may cause severe side effects.

Eligibility criteria - The key characteristics that one must have to participate in a clinical trial. This consists of both inclusion criteria (which are required for a person to participate in the study) and exclusion criteria (which prevent a person from participating). Types of eligibility criteria include age, gender, and disease characteristics.

Flare – Return of past symptoms or increase in current symptoms after a period of remission or lower disease activity. This may occur when tapering medication too quickly or overexerting oneself through exercise or stress. People with dermatomyositis may also notice flares with sun exposure.

Immune system – A network of cells, tissues, and organs that work together to defend the human body against attacks by harmful foreign invaders, such as bacteria, parasites, fungi, and viruses that can cause infection or disease.

Inflammation – Part of the immune system's natural response to heal an injury or fight an infection. Typical signs of inflammation include heat, pain, redness, swelling, and loss of function.

Innate immunity – Immunity that is present at birth and lasts a person's entire life. Innate immunity is the body's first response to a harmful foreign substance. It also includes barriers, such as skin, mucous membranes, tears, and stomach acid, that help keep harmful substances from entering the body.

Lymphocyte – A white blood cell that is part of the immune response system to infection or injury. T cells and B cells are types of lymphocytes.

Lymphodepletion – A kind of chemotherapy administered to destroy existing T cells prior to CAR T cell therapy.

Myositis-associated autoantibodies (MAA) – Proteins found in the blood of myositis patients as well as in the blood of patients with other autoimmune diseases. These autoantibodies are associated with myositis, and their presence can help guide treatment and understand the likely course of the disease.

Myositis-specific autoantibodies (MSA) – Proteins found specifically in the blood of myositis patients only. Anti-Jo-1 and anti-SRP are myositis-specific autoantibodies. Because they are unique to myositis, finding one of these autoantibodies in the blood is diagnostic for myositis. The specific type of MSA also helps guide treatment and understand the likely course of the disease.

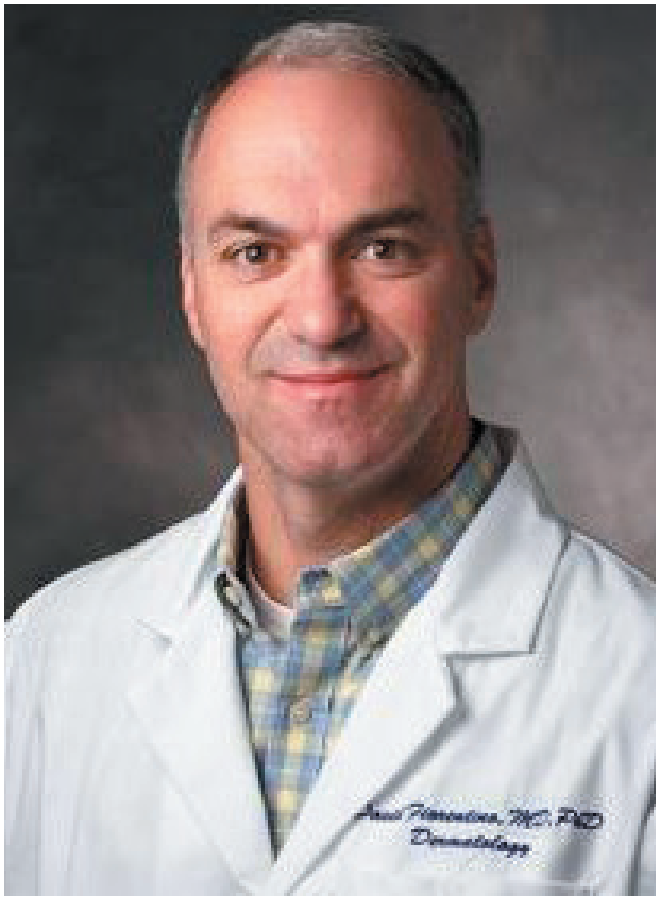
Naïve B cells – A B cell (immune cell) that has not yet been exposed to an antigen that circulates in the bloodstream looking for foreign substances such as viruses and bacteria (the antigen). Once the naïve cell is triggered by binding to an antigen, it targets the invader and destroys it.

Natural killer (NK) cells – A kind of lymphocyte that is part of the innate immune system. They quickly recognize and destroy disease-causing cells even before they stimulate the creation of antibodies in the body.

RNA-based CAR-T cells – CAR T cells that are created by inserting messenger RNA (mRNA) rather than DNA into the cell structure, making them less permanent and therefore less prone to stimulate severe side effects.

T cell (T lymphocyte) – A type of white blood cell involved in the acquired immune response. T cells are produced in the blood in response to a specific disease-causing substance such as a virus, bacteria, or toxin (antigen).

Treatment that's almost too good to be true!



Dermatologist Dr. David Fiorentino is excited about the possibilities of cell therapies to treat autoimmune conditions like dermatomyositis (DM). In collaboration with rheumatologists and bone marrow transplant specialists at Stanford University, he is conducting a small, phase 1b clinical trial testing KYV-101, a CAR T cell therapy that targets a protein called CD19 on the surface of B cells, that is being developed by the German biopharmaceutical company.

"We've been working with the company, Kyverna, for quite a while," Fiorentino says. "They have been working with a group in Germany led by Georg Schett, who have been the early pioneers for using anti-B cell therapy in lupus, myositis, and other autoimmune diseases."

Fiorentino, who is one of the world's leading experts in DM and is a member of TMA's Medical Advisory Board, is eager to gain experience examining the efficacy of such a treatment strategy, and to understand how this cell therapy affects people with different forms of DM, including clinically amyopathic DM and those with various autoantibodies (including MDA5). As a dermatologist, he is especially interested to see how the skin responds separately from muscle and other symptoms.

"The course of skin, muscle, and lung disease don't necessarily progress in parallel," he says. "We use slightly different therapies to treat skin than we do lung or muscle, and there's very little experience looking at what happens to skin disease with DM patients who are given the CD19 CAR T therapy."

Interestingly, while most clinical trials in myositis are required by the FDA to include patients with muscle weakness, this trial specifically allows those patients who have no muscle symptoms but do have severe skin disease.

Part of the excitement about CAR T cell therapy is related to expectations that this treatment has the promise of sustained disease remission, and, in some cases, what amounts to a cure due to an immune system "reset." It's understandable. The words "remission" and "cure" are not words often heard in the myositis community. Fiorentino is cautious, though.

"Honestly I don't think of it as one and done," he says. "I don't think this therapy is necessarily going to be a cure in all cases for all patients. I believe it's possible there could be long-term, durable remissions in some patients, but we just don't know. There is always the potential for relapse or inadequate efficacy in some patients."

So far there have only been a handful of people in the world who have received this unique, individualized, and very expensive treatment. Still, early reports indicate that it is remarkably effective. Patients have regained most if not all of their muscle strength and function within about three months, fatigue fades, and they feel better. Lung inflammation diminishes or even improves. Typically, even autoantibodies seem to disappear. And most—not all, though—have come off their medications completely.

"We haven't seen these kinds of responses with other kinds of therapies," Fiorentino says. "So there's understandably a lot of excitement. But there will be a long process of trying to find out what's the most effective, fast, safe, tolerable way to implement it. And then within a myositis diagnosis, there are many different subtypes to explore. So it's early days."

54 54 5454 Trial sponsor	Trial	Conditions	Contact
Bristol Myers Squibb	**NCT05869955**	Dermatomyositis Antisynthetase syndrome Necrotizing myopathy Polymyositis	BMS Clinical Trials Contact Center www.BMSClinicalTrials.com 855-907-3286 **Clinical.Trials@bms.com**
Cabaletta Bio	**NCT06154252**	Dermatomyositis Antisynthetase syndrome Necrotizing myopathy	Cabaletta Bio 267-759-3100 ext 4444 **clinicaltrials@cabalettabio.com**
Novartis (Rapcabtagene autoleucel)	**NCT06665256**	Severe refractory idiopathic inflammatory myopathies (IIM)	Novartis Pharmaceuticals 1-888-669-6682 **novartis.email@novartis.com**
Stanford (KYV-101, Kyverna)	**NCT06298019**	Dermatomyositis	By invitation only
U. Penn (KYV-101, Kyverna)	**NCT06152172**	Dermatomyositis Necrotizing myopathy Antisynthetase syndrome Polymyositis	Emily Marcuson 215-662-7179 **Emily.Marcuson@Pennmedicine.upenn.edu**

US studies only.
This field of research is changing rapidly, so this may not be a complete list of all current studies available.

Research on the horizon

Cell therapy represents an exciting new direction for the treatment of autoimmune conditions like myositis. In addition to CAR T cell therapy, other forms of cell therapy are in the early stages of development, including CAR NK, chimeric autoantibody receptor (CAAR), allogeneic CAR T, mRNA CAR T cell therapies, and others.

Based on the promising preliminary results in several autoimmune conditions including some sub-types of myositis, several clinical trial programs for these different cell therapies are underway to confirm their effectiveness and safety. Much is still unknown about these treatments, however, including long-term impact, how long the therapeutic effects may last, and if there are unexpected effects of genetically modifying human cells in this way. Those who may consider participating in a cell therapy clinical trial should proceed with a great deal of caution and ask as many questions as necessary to be sure they are comfortable with all the possible downsides of the trial.

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Tips for thinking about joining a clinical trial

Clinical trials are an important part of the process of testing new medications and treatments to see if they are safe and effective. All medical treatments and devices must be tested with human subjects before they are approved by the FDA and made available for use.

Because myositis diseases are rare, it's sometimes hard for a company to recruit enough patients to test their products and show significant results. That's why TMA encourages individuals to participate in clinical trials if they can.

If you're thinking about joining a clinical trial, it's important to ask the research team a lot of questions and feel like they have all been answered to your satisfaction. Here are some things to consider:

- What is the purpose of this clinical trial?
- Why is this treatment considered a good approach?
- Who is funding the trial?
- Who has reviewed the clinical trial protocol and approved it?
- Have patients been involved in raising awareness and helping to create the protocol?
- How will my safety and wellbeing be monitored?
- What if my condition gets worse or I have side effects?
- How long will the trial last?
- What is the commitment I am being asked to make for this trial in terms of time, physical discomfort, emotional stress, dislocation from my home and family, and other factors?
- What is a placebo and what if I get this instead of the real drug?
- How will I be informed of the results?
- What are the risks and benefits of this trial?
- How do the risks and benefits of this trial compare with other options?
- What kinds of therapies, procedures, and tests will I need to have during the trial?
- Will I be able to take my regular medications while I'm in the trial?
- Who will manage my medical care while I'm in the trial?
- How could being in this trial affect my daily life?
- Can I talk to other people in the trial?
- Are there things about the trial that I shouldn't talk to my social media networks, friends, and family about?
- Will I have to pay for any part of the trial? If so, what will the charges be?
- Will my health insurance have to cover any costs?
- Will I be compensated in any way for my participation?
- Who can help answer any questions from my insurance company or health plan?
- Will there be any travel or childcare costs that I need to consider while I am in the trial?

The gift of hope

TMA is able to support people with myositis and their families only because we receive financial support from generous individuals like you. During this time of holiday giving, we spoke with three TMA donors to find out why they give to TMA, the impact they see from their donations, and how it feels to be a TMA supporter.

Madge Chambers: Madge was diagnosed with myositis, a type now called necrotizing myopathy, over 20 years ago. After a lifetime as a tomboy and playing many sports—even as a mom—one day she found herself unable to run as fast as her five-year-old granddaughter. As other areas of weakness appeared, she began her search for answers. She and her husband attended their first TMA conference in 2008 and the experience was extraordinary. "The Medical Advisory Board (MAB) was so generous with their time and knowledge, and I met so many others with this disease most people have never heard of." Madge began giving to TMA at that first conference, and she has never stopped.

"This organization has given me so much. Members of the MAB helped me find good doctors, patients support each other, and TMA funds research to find better treatments and eventually a cure," Madge said. She feels good when she gives, and she loves supporting the staff who are passionate, capable, and committed. "They are just super! TMA is really headed in the right direction, and it feels good to support their work."

Lynn Murray: Lynn is Madge's daughter. "I only wish I had started supporting TMA sooner than I did," she said. At the time of her mother's diagnosis, she was living hundreds of miles away and raising young children in a military family. In 2014, her parents relocated to her neighborhood and Lynn became more involved with TMA after her father passed away. She attended doctor's appointments with her mother and became her travel companion for TMA conferences. "When I saw this amazing group offering support, understanding, and family encouragement to one another, I wanted to be part of it and help TMA grow."

Lynn and her father used to talk about how hard it was to watch Madge struggle with myositis. "To know that something as easy as donating could help educate people, support research, and prevent others from feeling alone in their myositis journey—I was so happy to get involved," Lynn said. No one she knows had even heard of myositis before learning about Madge's disease, and Lynn wants to broadcast information about myositis far and wide so many more people – especially doctors – know about it. She is inspired by her mother's commitment to helping others with myositis and wants to honor her generosity by supporting TMA. She also hopes TMA's research studies will improve things for patients in the future.

Frank Lipiecki: Frank became aware of myositis when his wife was diagnosed with inclusion body myositis (IBM) seven years ago. He was saddened to learn the disease had no treatment and no cure. "Research is the only way forward for people with IBM. We absolutely must have more funding, which is hard given how rare the disease is." Frank committed himself to supporting TMA financially, giving as much as he can to further research that might help others in the future. "There are way more good ideas out there than there is funding for them." Frank also sits on TMA's Board of Directors and chairs the Development Committee to help maximize research funding.

TMA invites you to consider joining these three generous donors by supporting TMA during this season of giving. Madge said, "Charity begins at home. If people affected by myositis don't give, who will?" Please check out **www.myositis.org/donate** for more information, and thank you very much for your support.

WHAT BRINGS YOU JOY?

Jenna Radke, medical student and TMA support group coleader

I find happiness in my friends, family, the serenity of nature walks, the escape of a good book, and countless other experiences that remind me of the beauty of life beyond illness. These are the things that sustain me, the parts of my life that dermatomyositis can never touch.

New Year resolution: Get involved with TMA affinity groups

TMA affinity groups are another way you can create supportive connections with others who live with myositis diseases and who also share your interests. Start your New Year by resolving to join one or more of these virtual communities from anywhere in the world! Find our full schedule of support and affinity group meetings on our **calendar**.

- **TMA Adelante! Grupo de afinidad** – For Spanish speakers – Meets every other month, see calendar
- **TMA Care Partner Affinity Group** – For those who love someone with myositis – Meets in their own breakout room with TMA's Nationwide Support Group on first Saturday of the month at 1pm ET
- **TMA Flying Solo Affinity Group** – For those who do not have a live-in care partner – First Wednesday at 8pm ET
- **TMA Men Managing Myositis** – Fourth Tuesday at 7pm ET
- **TMA Men of Color Affinity Group** – Meets quarterly, see calendar
- **TMA Military Veterans with Myositis Affinity Group** – Second Saturday at noon ET
- **TMA Rainbow Affinity Group** – For members of the LGBTQ+ community – Fourth Sunday at 5pm ET
- **TMA Women of Color Affinity Group** – First Thursday at 6:30pm ET
  TMA Women with IBM Affinity Group – Third Tuesday at noon ET

"I feel like I live a life of secrets. No one at work knows I have myositis, and although I am a member of the LGBTQIA community, I am not fully open about it. To have a space where I can talk about both having this chronic illness and how being different sometimes affects my care means a lot to me." - Anonymous

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