CONQUERING Sjögren's

March/April 2025

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April is Sjögren's Awareness Month

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Letter from Our President & CEO:

Raising awareness, amplifying patient voices, and driving progress in research and advocacy.

Janet E. Church
President & CEO,
Sjögren's Foundation

Spring is always a busy and exciting time at the Sjögren's Foundation, and this year is no exception! With Sjögren's Awareness Month and our upcoming National Patient Conference in April, we are fully focused on driving greater awareness, amplifying patient voices, and connecting you with the latest updates in Sjögren's.

April is Sjögren's Awareness Month

Each April, we use this time to showcase the many faces of Sjögren's, highlighting the patient stories that bring greater understanding of what it truly means to live with this disease. We know Sjögren's is so much more than dry eyes and dry mouth. Sjögren's looks different for everyone and by sharing real patient experiences, we help educate the public, healthcare professionals, and policymakers about the disease's full impact.

Join Us for the National Patient Conference

One of the best ways to stay informed is by attending our 2025 National Patient Conference, happening virtually on April 11th and April 12th. This year's event brings together top medical experts, researchers, and fellow patients for two days of sessions on the latest research, treatments and symptom management strategies. Our "Chat with a Doc" Q&A session with Dr. Donald Thomas is back! It is one of our most popular sessions, this is your chance to get answers straight from an expert.

Members receive a special discount, so if you haven't registered yet, now is the time!

Making Our Voices Heard

By the time you receive this newsletter, we will have participated in a Congressional Briefing on March 25th where we educated policymakers about why Sjögren's needs more attention and resources. These advocacy efforts are critical to pushing for change at the highest levels, and we're proud to represent the entire patient community in these important conversations.

State of Sjögren's

Earlier this year, we hosted our annual *State of Sjögren's* event, a virtual education program for healthcare professionals and researchers. This year's focus was on neurology, which is a complex and very challenging aspect of Sjögren's. In this issue of *Conquering Sjögren's*, we're bringing you key insights from the event that are most relevant to patients. As we continue to highlight the neurological/immunological impact of Sjögren's, we aim to push for more research and education so that medical professionals recognize and address the neurological implications of Sjögren's disease.

Celebrating Kathy Hammitt: A Lifetime of Impact

I am thrilled to share that Kathy Hammitt, our Vice President of Medical & Scientific Affairs, has been honored with the American Association for Dental, Oral, and Craniofacial Research (AADOCR) 2025 Jack Hein Public Service Award!

Kathy (who is a Sjögren's patient) has spent decades fighting for better patient care, advancing research, and making sure Sjögren's is taken seriously within the medical and scientific communities. Her impact is profound, and this award is a well-earned recognition of her leadership. Please join me in celebrating this milestone with her!

Finding Answers, Together

At the Sjögren's Foundation, we are always searching for more answers for patients. In this issue, we're providing an update on clinical trials that are shaping the future of Sjögren's treatment. We're also sharing some popular patient questions from our Inspire community.

Everything we do at the Sjögren's Foundation is made possible by the dedication and generosity of so many. I want to personally thank our Foundation staff for their unwavering commitment, our Board of Directors for their leadership, and our incredible donors and volunteers for supporting this important work. Most of all, I want to thank you, our members and patient community.

I look forward to seeing many of you virtually at the National Patient Conference and at one of our Spring Walk for Sjögren's events.

Janet Church

Janet E. Church

A Lifetime of Advocacy Recognized:

Sjögren's Foundation Leader Kathy Hammitt Receives the 2025 Jack Hein Public Service Award

Kathy Hammitt, Vice President of Medical and Scientific Affairs, Sjögren's Foundation, Receives the 2025 Jack Hein Public Service Award.

Kathy Hammitt didn't expect the email in her inbox. But when she read the words 'Congratulations on being selected for the 2025 Jack Hein Public Service Award,' she was stunned.

For decades, Kathy, who is Vice President of Medical and Scientific Affairs for the Sjögren's Foundation, has championed Sjögren's disease research and patient advocacy without seeking the spotlight. Receiving this award felt both surreal and deeply personal.

"I'm not an out front type person and I tend to work quietly behind the scenes and I enjoy giving others the spotlight for being an integral part of a great team," she shared. "So to receive such a distinguished award from an organization that I've long admired and supported just especially means so much to me."

Awarded by the American Association for Dental, Oral, and Craniofacial Research (AADOCR), this prestigious honor recognizes AADOCR members who have demonstrated exemplary service in public affairs by championing oral health research to a broad audience.

Kathy was recognized with the 2025 Jack Hein Public Service Award during the 54th Annual Meeting of the AADOCR in March 2025.

The award is especially significant because Kathy, a Sjögren's patient herself, knows that oral health is a life-altering aspect of Sjögren's disease. Sjögren's is a systemic autoimmune condition that directly impacts the mouth by attacking moisture-producing glands, leading to severe dry mouth, chronic oral infections, difficulty swallowing, tooth decay, and even an increased risk of lymphoma through the salivary glands.

"We need research to understand the mechanisms that lead to dry mouth so we can develop solutions. We need studies to learn how to prevent loss of saliva and tooth decay and find innovative and better solutions for restoring our teeth," she says. "But ultimately, understanding what's happening in the mouth and in the salivary glands can shed light on everything that's happening in Sjögren's."

For years, Kathy has pushed oral health to the forefront of Sjögren's care, making sure doctors, researchers, and policymakers see it as more than just a symptom, but as a fundamental part of patient well-being.

But her journey to this moment began long before she became a leader in the field—it started with her own diagnosis, determination, and an unexpected encounter that changed everything.

From Journalist to Advocate: A Life-Changing Diagnosis

Kathy never planned to dedicate her career to studying Sjögren's disease. She started out as a television news producer and writer in Washington, D.C., thriving in an industry that matched her passion for learning, storytelling, and uncovering critical issues. Coming from a family of educators and medical professionals— both parents were college professors, and her grandparents were physicians— she had always been drawn to the power of learning.

"Being a journalist gave me the excuse to learn about art, or learn about things in the government, or learn about so many different things," she says. "I love to learn and I love to get out there and talk to people."

Then, her own medical mystery changed everything.

After 17 years of unexplained symptoms, she was diagnosed with Sjögren's disease—a condition that forced her to leave behind the career she loved.

With little information available at the time, she took matters into her own hands, spending hours at medical libraries trying to understand her disease. It was during this search that she found a clinical trial for dry eye at Massachusetts General Hospital.

Even though she didn't yet have dry eye symptoms, she enrolled anyway, determined to take control of her health.

That decision led to a chance encounter that would change the course of her life.

While waiting for her appointment, she struck up a conversation with another patient and casually mentioned that someone needed to start an organization for this disease.

That woman was Elaine Harris, the founder of the Sjögren's Foundation.

"She told me she had just started a group, and I immediately told her I wanted to be involved—but only after I got back on my feet," Kathy recalled. "Elaine asked for a timeline, I gave her one, and on the exact day I told her I'd be ready, she called me."

She has been involved with the Foundation ever since.

Building a Movement for Change

From those early days of the Sjögren's Foundation, Kathy played an integral role in shaping the organization into what it is today. What started as a small grassroots effort grew a global leading organization in Sjögren's advocacy, research, and patient support.

"I love identifying the barriers to getting good care and learning more about this disease," Kathy says. "Then, I love bringing the right people to the table to address those barriers and create change."

Throughout her career, she has forged vital collaborations between researchers, clinicians, and patients, breaking down silos and ensuring that Sjögren's disease remains at the forefront of scientific and medical progress.

Her work has directly transformed the landscape of Sjögren's disease research and care, including but not limited to:

- Establishing the International Clinical Trials Consortium, working toward more successful clinical trials for potential therapies.
- Developing Clinical Practice Guidelines, creating clear, evidence-based care standards for rheumatologists, dentists, pulmonologists, ophthalmologists, neurologists and other healthcare professionals treating Sjögren's patients.
- Leading the push for Social Security Disability recognition, making it easier for Sjögren's patients to receive financial and medical support.
- Updating ICD medical codes, improving the ability of doctors to diagnose and track the disease properly.
- Driving the global shift to the term "Sjögren's disease", reinforcing the systemic nature of the condition.

Her ability to bring stakeholders together, identify barriers, and push for real change has helped drive some of the most significant advancements in the field.

Looking Ahead: The Future of Sjögren's

Though much progress has been made, Kathy believes the most transformative breakthroughs are still ahead. She is particularly focused on the potential of biomarker research and precision medicine, which could revolutionize diagnosis and treatment.

"I see huge changes in Sjögren's. Advancements have been accelerating in recent years," she says. "We need better diagnostic tools, and right now, too many people fall into the 'maybe' category. Biomarkers will help us determine exactly who has Sjögren's, what their individual risks are, and which treatments will work best for them."

She is also pushing for greater international collaboration to ensure that clinical trials are designed with the right patient populations, meaningful endpoints, and a clearer understanding of disease progression.

A Relentless Drive for Progress

Though her work is demanding, Kathy still makes time for the things that bring her joy like music, books, and being part of a book club. But nothing compares to the time she spends with her two children and two grandchildren, whom she calls the light of her life.

At the same time, her dedication to Sjögren's never wavers.

"95% of my time is devoted to constantly thinking about Sjögren's. The Foundation has been at the forefront of change, tackling barriers and bringing the international community together. I feel like it's a leading and formidable force in ensuring the patient is always front and center, so the millions who deal with Sjögren's every day have hope and the promise of a better future."

For Kathy, this award isn't just an honor, it's a challenge. There's still so much work to do, and as history has shown, when Kathy sees a challenge, she meets it head-on. ■

Pictured left to right: Nancy Carteron, MD, Kathy Hammitt, and Teresa Lawrence Ford, MD. Taken at the 2018 International Sjögren's Symposium in Washington, D.C.

STATE OF Sjögren's

2025 State of Sjögren's Overview

The *State of Sjögren's* is a virtual event for healthcare professionals and researchers from all specialties that provides a deeper look at the most recent information and research about Sjögren's disease (SjD). This year's topic was the neurological connections in SjD, which discussed the interplay between the immune and nervous systems in SjD. The topics included an overview of immune and nervous systems and their role in the clinical manifestations in SjD, the oral and ocular connections with the nervous system, perspectives on clinical management of patients with SjD presenting with neurological manifestations, the importance of communication and collaboration between rheumatologists and neurologists, and an update on the Foundation's most recent initiative— the central nervous system (CNS) clinical practice guidelines (CPGs).

Patient Experience with Neurological Manifestations

Our President and CEO, Janet Church, started with an overview of the patient experience with neurological manifestations. Neurological manifestations experienced by patients with SjD can include brain fog, trouble sleeping, anxiety, headache/migraine, poor/blurred vision, depression, sweating irregularities, dizziness, facial nerve pain, postural orthostatic tachycardia syndrome (POTS), and more.

Approximately 26% of patients from our *Living with Sjögren's* patient survey reported that their neurological symptoms (excluding fatigue) greatly impacted their life, and 25% of patients reported their fatigue was their most impactful symptom. An overwhelming 81% of patients responded that they have fatigue on a daily/weekly basis and 88% of those patients stated that treatments for fatigue are critically important. For those with neuropathy, headache, or migraine, patients reported as 2.5 times more likely to experience an emotional burden. These data emphasize the toll that neurological manifestations have on a patient's quality of life and the need for better care management and treatment for neurological conditions experienced by patients with SjD.

To improve quality of care for patients with neurological conditions, the Foundation has created peripheral nervous system (PNS) CPGs—published soon— and started the development of CPGs for the CNS. Providing guidelines for healthcare professionals leads to improved quality of care, reduced variations in practice, enhanced patient safety, and optimization of patient outcomes. The collaborative effort of our PNS CPGs has also led to the creation of a nomenclature guideline that aligns communication between rheumatologists and neurologists, which is important for consistent patient care.

The Science- Immune or Nervous System?

In the first session, Dr. Nancy Carteron, MD, FACR, a rheumatologist and clinical professor at the University of California Berkley and San Francisco, provided an overview of immunological and neurological interactions and how they mediate symptoms in SjD. When thinking about the immunological presentations of SjD, the focus is primarily on lymphocytic infiltration. Lymphocytic infiltration is caused by circulating lymphocytes, usually CD8+ cytotoxic T cells and/or CD4+ T cells. These lymphocytes can cause damage to the surrounding tissue not only in reference to the salivary glands or eyes, but also other extraglandular tissues including the gastrointestinal tract and pulmonary system. Dr. Carteron emphasized that lymphocytic infiltration is not the whole story and that neurological manifestations can have implications for SjD.

In SjD, the parasympathetic and sympathetic nerves that are part of the autonomic nervous system and control involuntary movements such as heart rate, blood pressure, and digestion can be affected. In both the eyes and salivary glands, a reduction in nerve fibers has been observed in patients with SjD. In the early 1990s, it was found that lymphocytes infiltrated the dorsal root ganglia (clusters of sensory neurons along the spinal cord) of patients with SjD and those patients developed sensory and autonomic neuropathies. When looking at scientific models of autoimmune disease, it has been shown that nerve and lacrimal (tear) gland function is decreased prior to lymphocytic infiltration— primarily CD4+ T cells in the cornea and lacrimal glands. These studies correspond to the experience many patients with SjD have, where they present neurological manifestations before testing positive for anti-SSA antibodies or sicca (dryness of eyes and mouth) symptoms occur and, therefore, often before a SjD diagnosis.

At the end of her talk, Dr. Carteron suggests that the answer to whether SjD is immunological or neurological is likely both. SjD is likely a representation of the homeostatic (process of allowing the body to properly adjust to external environment) imbalance of both the nervous and immune systems, suggesting that the inability to properly maintain internal balance of one system can disrupt the function of the other.

Oral-Neuro Connection

Dr. José Maldonado-Ortiz, DDS, PhD, is an oral medicine specialist and research investigator at the HealthPartners Institute in Minnesota. In this session, he discussed the neuro-oral axis, dry mouth, and patient care management. The oral cavity has three main types of salivary glands: parotid, submandibular, and sublingual, along with the minor salivary glands located throughout the mouth and the aerodigestive (tissues of the upper respiratory and digestive) tract. The salivary glands are directly linked to the brainstem (medulla oblongata and pons) by cranial nerves 5, 7, and 9, which send sensory signals to the brain and regulate saliva production.

The acini, specialized cells within the salivary glands that produce saliva, are controlled by peripheral nerves that help to contract these cells and release saliva. Peripheral nerve signaling also stimulates the production of important components of saliva such as proteins and mucins that aid in food processing and protect the oral cavity from bacteria by forming a coating on the gums and teeth. There are several factors that can affect the production of saliva including anxiety, depression, sleep, and certain types of medications. To further impact salivary production, the reduction of nerve fibers, inflammation, and antibodies like anti-Ro/SSA can block both PNS and CNS signaling and destroy nerve cells.

In terms of patient care, managing a patient's medication can impact the salivary production of patients with SjD. Anti-cholinergic drugs, which include antihistamines, certain anti-depressants, muscle relaxants, medications for urinary incontinence, and more, can decrease the production of saliva. However, muscarinic agonists such as pilocarpine and cevimeline, which are currently used in the management of dry mouth symptoms, can stimulate saliva production. On the horizon for new treatments for dry mouth is gene therapy. Gene therapy for the treatment of dry mouth in SjD focuses on the delivery of a key gene called aquaporin 1 to damaged salivary glands. Aquaporin 1 helps salivary glands produce more saliva by increasing the transport of water into saliva. Other gene therapies, such as the introduction of nerve growth factors like neurturin, may be used to reestablish or maintain the connection between nerves and salivary glands by regrowing parasympathetic nerves. Focusing on the neuro-oral axis may be key in comprehensive management of dry mouth symptoms. Dr. Maldonado-Ortiz emphasized that effective treatment of dry mouth demands a diagnosis aware approach, utilizing appropriate treatment, and supportive care options.

Ocular-Neuro Connections

In this session, Dr. Anat Galor, MD, MSPH, a professor of ophthalmology at the Bascom Palmer Eye Institute at the University of Miami and staff physician at the Miami Veteran Affairs Medical Center, discussed how understanding nerve function impacts how to think about dry eye disease in patients with SjD. Dry eye disease is an umbrella term that includes SjD-associated dry eye (SjD-DE). Since dry eye disease is not one disease, it is important to recognize that there are different presentations and, therefore, it is imperative that patients with dry eye also receive different treatments. Patients with SjD-DE may have symptoms that leave their eyes feeling dry, gritty, burning, and painful with some experiencing visual issues such as blurriness. Signs of dry eye include decreased tear production, epithelial disruption (breakdown of the protective layer of the cornea), or changes in stability of the tear film and ocular surface.

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Inflammation has long been thought of as a core mechanism in SjD. There are several ways to test inflammation in the eye including testing for the presence of MMP (matrix metalloproteinases) 9, which are proteins involved in inflammation and fibrosis (development of scar tissue). Newer imaging technology like confocal microscopy can help identify areas of inflammation in the eye. With confocal microscopy, immune cells called activated dendritic cells can be seen by special tags that cause them to fluoresce. Activated dendritic cells capture and present antigens to T cells, which elicits an immune response, and is a sign to eye doctors that inflammation is present. However, there is an issue with treating inflammation as the core mechanism- not every patient with SjD-DE has detectable inflammation and not every patient improves when treated for inflammation. This leads to finding other causes for disease symptoms.

The corneal nerves are responsible for sensing the environment of the eye and when there is a lack of tears, these nerves stimulate the secretion of tears that contain meibum (an oily substance produced by glands in the eyelids that prevents tears from evaporating) and growth factors for a healthy ocular surface. However, the nerves can send signals to the brain that there is dryness and pain at the level of the eye. If the nerves are activated inappropriately, there can be a decrease in tear production, abnormal meibum secretion, and epithelial disruption that signifies that nervous system dysfunction can drive signs and symptoms of dry eye. Nervous system dysfunction can involve the peripheral nerves, central nerves, and autonomic nerves.

Upon stimulation of the peripheral nerves after initiation of an inflammatory response, the nerves can either spontaneously fire or they can be overstimulated and cause more of a robust response. Abnormal peripheral nerve signaling in patients with SjD-DE can stem from decreased nerve density and increased nerve tortuosity (curvature of the nerves). There are several ophthalmological tests that can measure the sensation of the nerves in the eye such as touching the eye with a Q-tip or by using a device that delivers puffs of air. While many patients with SjD have abnormalities in both structure and function of the peripheral nerves, they do not sense these abnormalities in the same way- some are hypersensitive (increased sensation), and others are hyposensitive (reduced sensation).

The central nerves can also play a role in abnormal sensation including pain in patients with SjD. When the eye is stimulated in patients with SjD who have increased central nerve signaling, the undamaged skin around the eye is sensitive to the touch afterwards, which is called secondary hyperalgesia. To distinguish between peripheral and central nerve causes of pain, a patient is asked to rate their pain, given an anesthetic (pain-reliever) in the eye, and then asked to re-rate their pain. If the pain persists, the central nerves or other non-ocular sources are thought to be the cause and if the pain goes away then peripheral nerve causes of pain are further examined. Overall, patients with SjD-DE have more sensations after stimulus and suggest that in at least some individuals there is a central nerve component driving signs and symptoms of dry eye.

It is critical to understand how nerve dysfunction in SjD impacts how patients are treated for dry eye disease. The signs and symptoms of dry eye in these patients can tell us something different about their origin of pain. There are two subtypes that Dr. Galor described: 1) NK- neurotrophic keratitis (corneal nerve damage) and 2) NP- neuropathic pain. Patients with the NK subtype have decreased tear production, epithelial dysfunction, and decreased sensitivity. Treatment for the NK subtype includes giving back missing growth factors, which can be achieved using autologous serum tears and platelet-rich plasma eye drops as well as increasing tear production through various products such as nasal sprays that stimulate tear production. The NP subtype is characterized by neurological dysfunction that can have pain, burning, and sensitivity to light and wind. Treatment for the NP subtype focuses on neuromodulation, which requires determining the underlying nerve abnormality and figuring out the best way to target those nerves.

In conclusion, SjD-DE cannot be lumped into one category, but instead it requires the understanding that dry eye can take many forms and patients can have symptoms of dryness, actual dryness, epithelial dysfunction, and/or pain. Treatment of SjD-DE also requires a two-plan approach, where if treating the inflammation is not enough then understanding nerve abnormalities and treating those as well may improve patient care and reduce the morbidity of dry eye disease.

Perspectives on Clinical Management

In this session, an overview of the neurological aspects of SjD was presented by Dr. Goodman, MD, a neurologist and member of the Board of Directors for the Sjögren’s Foundation. Dr. Goodman anecdotally started the presentation by stating that he and another expert, Dr. Robert “Bob” Fox, would argue that

SjD is a neurological disorder. While this may not be a main thought in SjD research, a review of the prevalence of signs, symptoms, and diagnosis of neurological complications reported in the *Living with Sjögren's* patient survey and scientific literature does warrant further investigation.

Patients with SjD can present with almost any type of neurological condition, which includes headaches, migraines, facial pain, ocular pain, and other neuropathies. Neuromuscular junction disorders like myasthenia gravis, muscular dystrophy, and others, are relatively the only type of neurological condition that has not been seen or, at least in part, is very rare in respect to SjD. It is important to recognize that nervous system impairment may precede the development of sicca symptoms and autoantibody positivity in SjD. In one paper describing PNS complications related to peripheral neuropathy, 93% of patients in that study were diagnosed with SjD after neurological symptoms appeared. When treating patients with SjD, it is necessary to consider that other factors may be contributing to symptoms like fatigue and brain fog rather than being related to pain, feeling unwell, or medications.

SjD may impact several CNS (brain and spinal cord) and PNS (nerves, nerve root, and muscle) complications. Headaches may be seen in 50-75% of individuals with SjD and can present as migraine, tension-type headaches, postural headaches, and others. There is some literature that also suggests that headaches can be immunoresponsive in patients with SjD, suggesting that headaches may be a distinct manifestation of SjD. Cranial neuropathies are also very common in SjD, where any cranial nerve can be involved simultaneously or sequentially, and can also be caused by inflammation of the meninges (the lining of the brain that wrap around the cranial nerves). Patients with SjD can also have encephalopathies, which can cause neuropsychiatric manifestations that affect cognitive function (like brain fog), mood, and can cause seizures. Neuropsychological assessments may be warranted in some cases to further evaluate those types of symptoms.

Peripheral neuropathies are one of the most common neurological involvements in SjD, specifically in childhood SjD. Small fiber neuropathy usually manifests as numbness, pain, and tingling in the feet affecting nerves that are furthest from the spinal cord, but in SjD, these symptoms may first manifest in the hands. Identification of peripheral neuropathy may be missed in physical examinations as strength reflexes are normal, so it is imperative to perform tests to observe diminished sensory perception in the feet and hands.

Autonomic dysfunction is much more common in SjD than lupus. In SjD, these can manifest as blood pressure and heart rate issues, gastrointestinal dysmotility, and urinary impairments. Interestingly, irregular breathing in patients with SjD who don't have lung disease can be caused by autonomic dysfunction. Treatments for nervous system involvement can include several forms of immunotherapy such as low dose naltrexone, hydroxychloroquine, rituximab, and others. Overall, it is important to identify the presence and severity of nervous system impairment and whether that nervous system impairment responds to immunotherapy.

Communication and Collaboration: Intersection of Rheumatology and Neurology

Dr. Ghaith Noaiseh, MD, associate professor of medicine and director of the Sjögren's Center at the University of Kansas, discussed the recent collaborative work of rheumatologists and neurologists on behalf of the Sjögren's Foundation. With the impact of PNS involvement on the quality of life of patients with SjD, it was important to bridge the gap between neurologists and rheumatologists in the treatment of their PNS conditions. There is also a wide spectrum of PNS manifestations observed in patients with SjD, which could range from mild to severe and disabling. Evidence based guidelines are essential resources for informed clinical decision making by combining the best evidence available with clinical expertise of practitioners and patient's needs. In 2015, the Foundation developed the first U.S. based CPGs for the management of ocular manifestations in SjD. The CPG initiative, started in 2009, aimed at improving the quality and consistency of care for patients with SjD, while also defining the areas for future research.

After a three-year effort, the PNS CPGs are completed and awaiting peer-reviewed publication. This work brought to light the many diagnostic challenges that neurologists and other practitioners face while evaluating patients suspected of having SjD. Asking patients about the presence or absence of dry eyes and dry mouth may not be enough to adequately screen patients for SjD as there is plenty of evidence of the poor correlation of dryness symptoms felt by patients and clinically measured dryness. As neurological symptoms may precede sicca symptoms, a patient may have SjD, and both the practitioner and the patient are unaware.

Neurological manifestations are more common in certain subsets of patients with SjD. For example, small fiber neuropathy is more commonly seen in patients that tend

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to be seronegative for anti-Ro/SSA antibody and the diagnosis of this subset of patients could be easily missed without a lip biopsy. As lip biopsies are not routinely performed in many practices and academic centers, this adds to the challenges of establishing a SjD diagnosis. A study revealed that up to 40% of patients with POTS had evidence of SjD, when appropriately tested for SjD using SjD-specific autoantibodies or lip biopsy. This is an example of when patients are seen by one specialist, but the underlying disease is not being identified. Rheumatologists also have challenges as they are busy addressing sicca symptoms and other systemic manifestations of SjD but may not have the time or the expertise to perform detailed neurological examinations.

After performing literature searches to establish the PNS CPGs, it became aware that neurologists and rheumatologists have different perspectives when identifying and managing the PNS manifestations of SjD. Much of this is due to the variability of terms characterizing the nature of PNS dysfunction and the heterogeneity in which the PNS manifestations are classified. The misalignment of the classification system terms for patients as well as the non-uniform nomenclature were challenging to reconcile and interfered with communication in the clinical care of patients and the review of literature for the CPGs. With these issues in mind, the PNS guideline panel undertook an effort to create shared definitions of the types of PNS manifestations observed in patients with SjD which was pivotal in created developing the PNS clinical guidelines. In summary, the communication gap identified by the Sjögren’s Foundation PNS clinical practice guideline panel highlighted the challenges for multi-specialty collaboration in clinical management and research.

CNS Clinical Practice Guidelines

Dr. Arun Varadhachary, MD, PhD, professor of neuromuscular neurology and neurohospitalist section head at Washington University, discussed the next CPGs, which focuses on the CNS. The guideline process has five milestones: 1) systematic literature review, 2) draft recommendations and best practices, 3) consensus achievement, 4) draft manuscript, and 5) publication. Currently, the CNS CPGs are in the systematic literature review phase where the panel (made up of 50% neurologists and 50% rheumatologists) is putting together evidence-based questions about CNS involvement in SjD to address in the literature. Patient representatives are also asked to review these questions to make sure the questions are relevant to them and their care. This process requires a rigorous methodology to find a strong foundation from clinical research used to make clinical care decisions. Once recommendations and best practices are established, an external review will be sent to other providers and patients to comment on the recommendations and best practices. Similarly to the PNS CPGs, the challenge of having a shared language among providers has to be resolved first. Another challenge is the variability of CNS involvement and prevalence data for patients with SjD. The goal of the CNS CPGs is to not only provide improved patient care, but to also get a better understanding of how frequently CNS manifestations such as anxiety, brain fog, mood disorders, and cerebral vasculitis among others presents in SjD. ■

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Sjögren's Foundation

National Patient Conference 2025

Registration is Open!

Virtual National Patient Conference 2025
Connect, Learn, and Thrive!

Friday, April 11th – 12:30 PM - 5:30 PM (ET)
Saturday, April 12th – 12:30 PM - 4:30 PM (ET)

Join us for an exciting and empowering virtual experience designed to help you connect, learn, and thrive while living with Sjögren's disease! This year's conference will bring together experts, researchers, and patients for a two-day event focused on education and community.

What is the National Patient Conference?

The National Patient Conference is the Sjögren's Foundation's largest educational event, bringing together patients and talented medical experts to provide the latest information on Sjögren's disease. This virtual event allows you to participate from the comfort of your home while still benefiting from live expert sessions, Q&As, and patient community connections.

Conference Topics

This year's event will cover:

- Overview of Sjögren's
- Oral and ocular management
- How Sjögren's disease affects your ears, nose, and throat, nervous system, and other parts of your body
- Latest Sjögren's research and what we are learning about different patient profiles
- Back by popular demand! "Chat with a Doc" with Dr. Donald Thomas (Live Q&A on both days)

The full agenda can be found at sjogrens.org/npc

Registration

Members– $80 – When registering please remember to use your Discount Code at checkout to receive your $20 member discount! Not sure where to find the code? Check your email — all National Patient Conference emails to members will include the discount code.

Non-Members- $100 – Learn more about conference topics, speakers, agenda and registration at our conference event page at sjogrens.org/npc or scanning the QR code.

Please Note: Registrants must have a device with internet access to join the conference. If you register and are unable to attend, or would like to replay a presentation, a video recording will be available after the conference to review.

QUESTIONS?
Call (301) 530-4420,
email info@sjogrens.org

Sjögren's
FOUNDATION

A Supportive Space Just for You – *Join Inspire!*

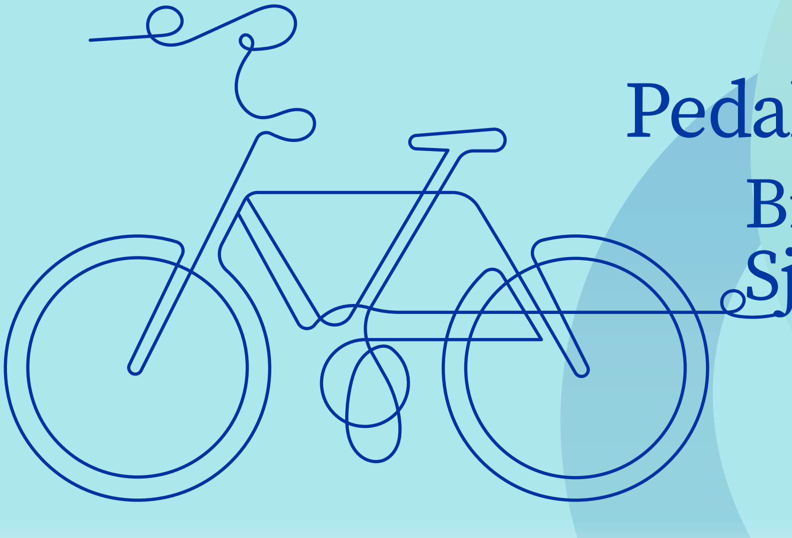
Looking for a place where people get what it's like to live with Sjögren's disease? The Sjögren's Foundation Inspire Community is where patients and caregivers connect, share experiences, and support each other.

- *Ask questions & get real experiences*
- *Find support from people who understand*
- *Get insights on symptoms, treatments & daily life*

inspire™

Join Today!

The Sjögren's Foundation Inspire Community is a peer-to-peer forum. Discussions are not monitored by medical professionals, and posts do not reflect the views of the Sjögren's Foundation. Always consult a healthcare provider for medical advice.



Pedaling with Purpose:
Brian's Bike Ride for Sjögren's Disease

When Brian Stallcop embarks on his 309-mile cycling journey from London to Paris this July, he won't just be crossing international borders, he'll be riding for a cause that hits close to home. His wife, Shawna, was diagnosed with Sjögren's disease just a few years ago after a long, frustrating search for answers. Now, Brian is using his passion for cycling to raise awareness and funds for the Sjögren's Foundation.

"What's really awesome about this ride… we finish in Paris the day before the Tour de France, and follow the route down the [Champs-Élysées] and pass the Arc de Triomphe, and we finish at the Eiffel Tower," Brian said. "So that's going to be pretty fun…That's a bucket list thing."

Brian's four-day ride, taking place July 23-27, is part of an organized event where riders choose their cause. Brian debated different causes but chose to ride for Sjögren's after realizing the answer was right in front of him.

"I actually had a couple different ideas, and then I realized that the purpose was sitting across the dining room table from me," he said. "Sjogren's is kind of a struggle. It flies under the radar. It took [Shawna] years to get a diagnosis. It's very hard to find somebody who understands it unless you're in a major city with a teaching hospital. I mean, your average internal medicine doc really doesn't have any idea."

Shawna, a family nurse practitioner, has used resources from the Sjögren's Foundation to educate not only herself but also her own medical providers. "She's even used some of the resources, I think from your website, to give to her medical providers to try to bring them up to speed," Brian explained.

Brian Stallcop plans on cycling 309 miles, in honor of his wife Shawna, to raise awareness and funds for the Sjögren's Foundation.

Brian is no stranger to endurance rides—he previously cycled 500 miles through Oregon—but preparing for this event has its own challenges, especially through the harsh Oregon winter.

"I have a Peloton, so I did a 90-minute ride on my Peloton yesterday," Brian said. "While it's snowy outside, I'm doing the Peloton at least three days a week. And then I'm trying to cross-country ski one to two days a week. As the weather turns, that will transition to outdoor cycling. I'll probably be trying to get at least a hundred miles a week on my road bike leading up to this."

While his fitness base is solid, Brian admits that the real challenge is something much simpler. "It's really just, honestly, my base fitness is fine, but it's training your butt to be in the saddle that long," he laughed.

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More than just a fundraiser, Brian’s ride is a way to bring greater awareness to Sjögren’s disease.

“I think with so many diseases or disabilities, they don’t always manifest themselves visually,” he said. “So you can be sitting next to a person with Sjögren’s and have no idea the challenges that they’re facing.”

That’s why Brian is sharing his journey far and wide. He’s focusing his efforts on social media, his Rotary Club, and conversations with friends and family. He’s also armed with a QR code for instant donations at events, and as the ride gets closer, he plans to ramp up his outreach even more.

Be sure to follow us on social media, where we’ll share updates on Brian’s journey, including highlights from his ride!

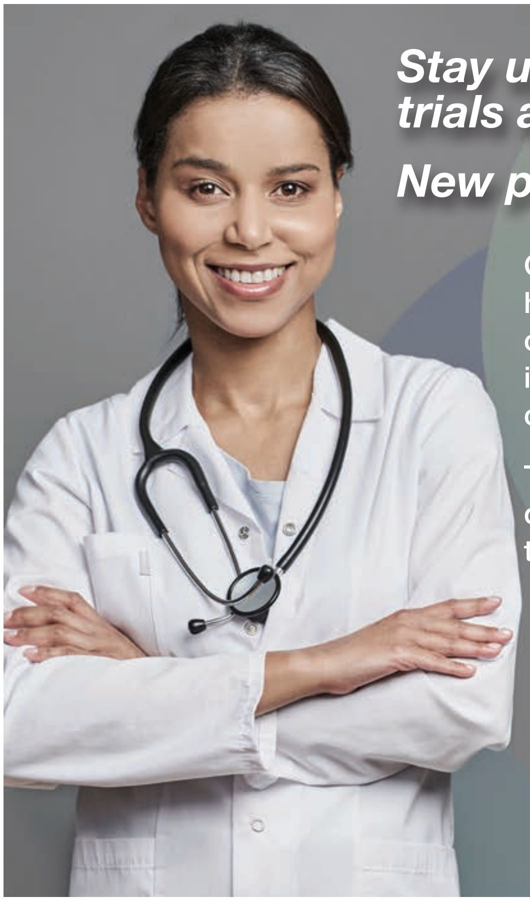
“This ride is a bucket list item for me, but it’s also a way to support Shawna and others living with Sjögren’s,” Brian said. “I want more people to know about this disease and understand the challenges patients face.”

Thank you Brian for raising critical awareness and support for the Sjögren’s community. We’re cheering you on!

Shawna and Brian Stallcop

Interested in raising money for the Sjögren’s Foundation, please email us at info@sjogrens.org. ■

Scan to support Brian's efforts.



Stay updated on current Sjögren’s clinical trials and how they can benefit you.

New phase 2 trials are happening now!

Clinical trials are a crucial element in medicine and healthcare to help develop drugs that will treat or possibly cure certain diseases. Researchers use clinical trials to test if a drug works, how well it works, how safe it is and how it compares to any currently available treatments.

The Sjögren’s Foundation has a section on its website devoted to clinical trials in Sjögren’s and a listing of clinical trials that are currently recruiting Sjögren’s patients.

Sjögren’s
FOUNDATION

April is Sjögren's Awareness Month

April is a time to unite, celebrate our Sjögren's community, and raise awareness about this often-misunderstood disease. No matter your connection—whether you live with Sjögren's, care for someone who does, treat patients, or advocate for the cause—this month is an opportunity to make a meaningful impact and support those affected!

Every day in April, we will highlight a different patient and show a glimpse into their life with Sjögren's. We will also use this campaign to give a unique "patient-to-patient" viewpoint and dive deeper into various Sjögren's topics with advice directly from other patients. We hope these stories will help create a better understanding of this complex disease and let all patients know that there is support through this community. In addition to sharing these powerful stories, we'll also be providing educational resources and ways to support our mission.

Get Involved

Visit **sjogrens.org/sjogrensmonth** to learn about all the ways you can participate, including:

- Share your story and help us amplify the stories of others
- Test your Sjögren's knowledge by taking our fun and interactive Sjögren's Month quiz
- Spread awareness and share our campaign with **#ThisIsSjögrens** and tag us
- Attend the National Patient Conference and gain insights from experts
- Join a Spring Walk for Sjögren's and raise awareness and support

Join us for Sjögren's Awareness Month at sjogrens.org/sjogrensmonth.

Promising Treatments of Sjögren’s on the Horizon

After decades of only symptom-relieving treatments for patients with Sjögren’s, there are finally several promising new therapies for systemic disease in various phases of clinical trials. Although this is a very exciting time for Sjögren’s, it is also a challenging time because we have many clinical trials looking for participants all at the same time. We need more formally diagnosed Sjögren’s patients to call and consider enrolling! There are six new mechanisms of action (different ways drugs cause an effect) being tested in clinical trials right now for formally diagnosed patients. For each trial, a patient must have a positive anti-SSA/Ro test and/or a positive lip biopsy test to qualify for the trial.

With the heterogeneity (wide variability) of signs and symptoms of Sjögren's in our patient population, having this many options means a greater chance that one of these drugs could potentially work for you. However, if we do not have enough patients enrolling in all the clinical trials, then some therapies may not be able to complete the trial, and, therefore, not come to market even if the drug is promising. Currently, there are no clinical trials for those patients who have been told they have Sjögren’s but are not positive for anti-SSA/Ro or lip biopsy. Patients who are negative for these tests have not been well-characterized or scientifically understood and so have not been included in most clinical trials. As a result, benefits and risks of therapies have not been studied in this group of patients, and therapies have not been designed that could prove effective at a reasonable risk for these patients. The Foundation is working hard to ensure research is expanded on this group of patients!

In this article, you will learn more about participating in clinical trials and why we encourage you to call a trial site near you. Just go to our clinical trials web page, scroll down the page to the state listings, and look for a study near you at sjogrens.org/trials. You can also

Phase	*Who*	*Purpose*
I	Small population of healthy individuals and/or individuals with a disease or condition	Tests for drug safety and drug dosage
II	Up to several hundred individuals with a disease or condition	Tests for effectiveness in treating a disease or condition and determines adverse effects or risks associated with the drug
III	Several hundred to several thousand individuals with a disease or condition	Usually longer in duration, demonstrate whether a product offers a treatment benefit to a specific population and provides most of the safety data
IV	Several thousand individuals with a disease or condition	Post-market safety monitoring

learn more from the article, “Clinical Trials and You” in the November/December 2023 issue of *Conquering Sjögren’s*. All current clinical trials can be found at clinicaltrials.gov.

What is a clinical trial?

A clinical trial is a research study used to determine the safety and effectiveness of a potential therapy for an indicated medical condition. Clinical trials are divided into four phases with each phase focused on one aspect of the drug’s safety and effectiveness within a specific population.

Why do clinical trials matter to you?

Participating in clinical trials for Sjögren’s makes you a partner in scientific discovery and it’s an opportunity to learn more about your Sjögren's and potentially receive a therapy that improves your quality of life. You could be involved in a study that may change the course of treatment for patients with Sjögren’s in the near future. There has never been this many clinical trials vying for participants with Sjögren’s nor clinical trials that also include patients with different severities of disease and symptom burden. Clinical trials depend on volunteer participation and without participation, the discovery and application of better treatments does not happen.

What are eligibility requirements to participate?

Each clinical trial has different eligibility requirements, but they all require proof that a patient has Sjögren's based on the currently accepted classification criteria of a positive anti-SSA/Ro and/or lip biopsy (Note that classification criteria are for selecting patients for clinical trials and not for diagnosis in the clinic. It is important to companies conducting trials and to the Food and Drug Administration (FDA) that approves therapies that a patient population is clearly defined for targeted therapies). These medications were designed with this specific phenotype (observable characteristics) of patient and therefore, an understanding of the risk profile for people receiving the therapy. The trial itself will determine the real risk/reward of the therapy. All requirements needed to start a clinical trial and to stay in a clinical trial will be provided during the screening and informed consent processes. The screening process ensures patients meet the basic criteria to join a clinical trial and determines if they can safely participate in that trial by reviewing medical history and performing a physical examination, which may include laboratory tests. Participants may also be required to meet other criteria to stay in the study after enrollment, such as going to scheduled appointments, having clinical tests performed, stopping certain medications, and more.

What is informed consent?

Informed consent is a process where clinical researchers give you detailed information about the study. During the informed consent process, you will be informed of the following:

- The purpose of the study and its objectives
- Research procedures, clinical protocols, and methods including duration and how many office visits you are required to complete the study
- Expected benefits from the study
- Potential risks and discomforts
- Measures used to protect your identity and data
- Contact information for questions or concerns

It is important to know that participating in a clinical trial is voluntary throughout every step. Even if you consent during this process, you can withdraw from the study at any point.

What are some potential benefits of being in a clinical trial?

When participating in a clinical trial, the guaranteed benefit is that you are providing researchers with information that can help improve treatments and whether a new drug gets approved or not. Due to rigorous testing and requirements by the clinical trial, you may receive medical care and comprehensive testing for free. Since many of the new clinical trials are monitoring outcomes of systemic disease, it is likely that you will receive comprehensive follow-ups and be monitored better and/or more frequently during a study. Some trials also pay you to participate, and you can ask about this when you call a trial coordinator. Be sure to ask the clinical team what medical care-associated costs are covered by the clinical trial and if there are any costs to you. You can always ask to have costs waived or paid by the pharmaceutical company.

Every trial has a placebo group (people who do not receive the medication and are not told this) to compare the data from patients taking the medication and those in the placebo. While potentially receiving a new treatment is an appealing benefit, there is no guarantee that you will be in the group that receives the new treatment or the placebo group that does not. There is no guarantee that the treatment will work either. However, in many clinical trials, it may be their protocol to give the new treatment to the placebo group after a

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"Treatments" continued from page 17 ▼

certain amount of time, if positive outcomes are met from the treatment group.

Frequently Asked Questions

What if I am not eligible for a clinical trial?

Even if you are not eligible to participate in one clinical trial, you may qualify for another. With six different mechanisms and other studies that look at both severity of disease and symptom burden, this increases the chance that you may be eligible. If you still cannot find a clinical trial to participate in, you can help the Foundation and other patients with Sjögren's by spreading the word about current clinical trials and communicating the importance of participating in clinical trials. If you are interested in enrolling in a trial but there is not a trial near you, please complete this form: https://share.hsforms.com/1nhXfRlhtQeSkeGeZhykSOw3619

What happens if there are no clinical trial sites near me?

If a clinical trial site is within a feasible travel distance to you, you may ask if the clinical trial site will reimburse you for travel. The Foundation recognizes the need for more widespread clinical trial sites and is actively working with pharmaceutical companies to establish connections with doctors around the U.S. with the capability to become clinical trial sites in the future.

What if I don't have the time due to work or other obligations to participate?

You can always ask a clinical trial if they can reimburse you for your time. If you have children that need to be taken care of, you can also ask if they can reimburse you for daycare, if you can bring your children with you, and/or if they have daycare on-site.

Does my current medicine affect my eligibility?

During the screening and informed consent process, you can ask about eligibility requirements and requirements to stay in the trial. You may have to discontinue certain medications for a period of time while you are involved in a clinical trial. It would be helpful to bring a list of current medications and dietary/nutritional supplements that you may take so that you can determine whether you have to discontinue any medications and if you are eligible to participate. However, most trials allow the continued use of hydroxychloroquine, if you have been stable on the medication for a certain amount of time.

Do I have to stay in a clinical trial if I no longer want to participate?

You can disenroll from a clinical trial at any time. Clinical trials are voluntary throughout the whole process from screening to the end of the trial. The study investigators have protocols on whether to include your data in their study or not. If you have any adverse effects during the trial, you may be asked to discontinue the study for your own safety. Your emotional, mental, and physical health are the priority.

How is my health monitored in a clinical trial?

This is dependent on the clinical trial. Since most of the clinical trials out now are for systemic disease, your health may be monitored by biomarkers/antibodies from blood or tissue samples, laboratory tests, quality of life questionnaires, and more. The protocol for the clinical trial you are willing to participate in should be explained to you in detail during the informed consent process.

What if I start feeling better during the trial, can I stay on the clinical trial treatment?

During the clinical trial, it is important to communicate how you are feeling with your medical care team. If you start to feel better while receiving treatment during the clinical trial, your doctors will decide whether to keep you on the treatment or not. Remember that you may or may not be receiving the treatment and your doctor may also not know as many clinical trials do not tell the doctors to prevent bias results.

After the clinical trial is over, you will likely not be allowed to continue the treatment you were receiving as the treatment is still under investigation. However, if the drug is approved, some pharmaceutical companies may offer a discount on future treatment— another question to ask during informed consent.

If you are interested in participating in clinical trials, please stay up to date with news from the Foundation and check out new clinical trial sites at **sjogrens.org/trials**. ■

IN MEMORIAM

In Memory of Heidi Ann Burke
John Burke

In Memory of Nancy Doherty
Christine Palmucci

In Memory of Colleen Faust
Mary Rucke

In Memory of Edna French
Debra MacKay
Robin Salzano

In Memory of Carol Ann Gergel
James Gergel

In Memory of Jan Gordon
Kevin McCaffrey

In Memory of Elaine Harris
Linda Harris

In Memory of Lari Lopp
Virginia Garretson

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Gail Johnson

In Memory of Ron Parker, Jr.
Kathy Hosea

In Memory of Ellen Peterson
Carl Peterson

In Memory of Demetra Petros
Nicole Petros

In Memory of Ella Sisler
Darla Rae
Joe Sisler

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In Honor of Gillian
Ladean Flemming

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If you would like to receive this newsletter but are not currently a Member, please contact us at (301) 530-4420

Walk for Sjögren's 2025

STEP UP for Sjögren's

Join us and help raise critical funds to:

- DRIVE GROUNDBREAKING RESEARCH
- SUPPORT PATIENT & PROFESSIONAL EDUCATION
- ADVOCATE FOR PATIENTS
- BUILD A STRONG, SUPPORTIVE COMMUNITY

April

VIRTUAL Southeast Walk for Sjögren's
Saturday, April 5, 2025

VIRTUAL Southwest Walk for Sjögren's
Saturday, April 5, 2025

May

LIVE Philadelphia Tri-State Walk for Sjögren's in Philadelphia, PA
Saturday, May 10, 2025

VIRTUAL National & Mid-Atlantic Walk for Sjögren's
Saturday, May 31, 2025

VIRTUAL Colorado Walk for Sjögren's
Saturday, May 31, 2025

June

LIVE Midwest Walk for Sjögren's in Madison, WI
Saturday, June 21, 2025

Learn More and Register Today at:
sjogrens.org/walks

Questions? Email
walks@sjogrens.org

sjogrens.org/walks