

CONQUERING Sjögren's

November/December 2022

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A Letter from your CEO, Janet E. Church

Every year, I am surprised at how quickly the holiday season arrives! But here we are, and I am already excited to make cookies, watch holiday movies, and gather with loved ones. I also take this time to appreciate what has been accomplished throughout the year and solidify my intentions for the coming year.

Reflecting on the Foundation's accomplishments, I am immensely proud of what we have achieved to support and educate patients and to drive change in the Sjögren's community. Last spring, we witnessed our most successful April Awareness month ever. We kicked off our first day of thirty patient stories with Carrie Ann Inaba of *Dancing with Stars* and closed the month with Venus Williams sharing her story. We published our Sjögren's Book 5th Edition with new information about Sjögren's and we delivered our National Patient Conference to over 1,000 patients.

Other highlights from the past year include an increase in medical provider education on Sjögren's. We began the year with the new State of Sjögren's conference in January, produced a primary care provider continuing medical education (CME) course called *Spotting Sjögren's* which is available through February 2023, presented posters and sessions at the International Symposium on Sjögren's, and attended the American Autonomic Society and the American College of Rheumatology conferences. Whenever we speak to providers, we leverage the *Living with Sjögren's* survey data to drive home that **Sjögren's is serious, systemic, and prevalent.**

In this issue

Some of our most important successes are highlighted in this issue of *Conquering Sjögren's*. The world's top Sjögren's experts gathered in Rome in September to learn about new research and to move the study of Sjögren's forward. A summary of the event is inside as well as my personal highlights, from the patient perspective, of the International Symposium on Sjögren's Syndrome.

Yes, you read that right...I said "syndrome," which was the official title of the conference because it is still the official medical name of our disease. The Foundation has been leading the charge for nomen-

clature change to drop the word "syndrome" from the name of our disease and to address other language currently associated with the disease. Please read about the importance of this initiative inside.

We also cover how your donations are put to use in research! Our newest research grant awardees are highlighted as well as an article updating you on the important five-year private/public partnership called AMP[®] AIM. This research will likely change what we know about Sjögren's, which could change how we diagnose and treat patients. The Sjögren's team that won the grant award for this program is called the Sjögren's Team for Accelerating Medicines Partnership (STAMP). There are four primary investigators (PIs) representing UCSF, Johns Hopkins, OMRF, and NIDCR with team members from UC Berkeley, NYU Langone, and HSS. The Foundation's Kathy Hammitt is also on the STAMP team.

We also included an article on the numerous clinical trials that are specifically for Sjögren's patients! We hope that in the next 3-5 years we see a new therapy come to market that can help us all live a better quality of life. However, it will take more patient enrollment to make this a reality.

Moving Forward

As we move forward into next year, we are increasing our provider education programs, growing our research investments, and there will be a strong emphasis on the many clinical trials in process. We will always have our patient support and education programs and be assured that everything we do at the Foundation always has the patient front and center.

As we say goodbye to 2022 and begin to welcome in 2023, I want to thank the Foundation staff for their commitment to patients, our volunteers who bring Sjögren's education and support to local communities, and our Board of Directors who give their time to ensure our mission is moving forward. And I especially want to thank you!

I am grateful for your support and I am honored to lead this organization as we fight together to conquer the complexities of Sjögren's. Wishing you a happy and healthy holiday season! ■

Sjögren's Foundation Announces New Grants for FY23

The Sjögren's Foundation is excited to announce the selection of three new research grant recipients for the current fiscal year, which includes one High Impact Grant and two Pilot Grants. Additionally, the Foundation has provided no-cost extensions to a portion of our current grantees to allow for extra time to continue and complete their work.

High Impact Grant: 2022-23



Mohammed Haj Dezfulian, PhD
Postdoctoral Fellow, Brigham and Women's Hospital, Harvard Medical School, Boston, MA

Project Title
Mapping the Specificity of CD4+ Lymphocytes in Sjögren's Disease

Abstract

Sjögren's disease is an autoimmune disease that affects an estimated 4 million people in the US and is characterized by dry eyes, dry mouth, and other systemic manifestations. The cause or causes of Sjögren's are not clearly understood. However, genetic and environmental factors could play a significant role and likely work in concert. One of the hallmarks of the disease is the immune cell infiltration found in the salivary and lacrimal glands. Various observations have implicated these immune cells in the pathogenesis of Sjögren's disease. This proposal seeks to decipher the specificity of these immune cells. Identification of the full breadth of antigens recognized by these T cells can uncover mechanisms that underlie the pathogenesis of the disease and revolutionize approaches to disease diagnosis and prognosis, ultimately leading to the development of various immunomodulatory therapies.

Pilot Grants: 2022-23



Thomas Grader-Beck, MD
Assistant Professor of Medicine, Johns Hopkins University

Project Title
Leveraging Electronic Health Record Systems to Establish a Multi-Center Collaboration Platform for Quality of Care and Clinical Research in Sjögren's Disease

Abstract

Modern Electronic Health Record (EHR) systems provide a unique opportunity to analyze large populations of patients with Sjögren's disease to gain insight into disease presentation, therapy and care gaps. Unfortunately, a tremendous amount of clinical data in EHR systems is not stored in a structured format and therefore difficult to analyze and share. We have developed a comprehensive clinical module for Sjögren's disease that is integrated into the EHR system and allows high quality standardized data collection. We propose to integrate this module into the EHR system at two collaborating sites initially. We will report on the implementation process as well as clinical characteristics of the Sjögren's population at each site. If successful, implementation of the module can be expanded to other institutions and a data sharing platform can be developed. Such a platform would provide a highly valuable tool to improve quality of care and research in Sjögren's disease.



Tomas Mustelin, MD, PhD
Professor of Medicine, University of Washington

Project Title
Pilot Study of Disease-Specific Expression Modules in Sjögren's Neutrophils

Abstract

This proposal will carry out RNA sequencing of immune cells isolated from the blood of 30 patients with Sjögren's and 10 healthy volunteers. The resulting large data set will be mined for new clues to the cause and development of Sjögren's. In particular, we will identify genes and gene sets that are turned on in Sjögren's, but not in the same immune cells from patients infected with the SARS-CoV2 (the coronavirus causing the current pandemic). We have chosen this comparator because the disease (COVID19) has many symptomatic and molecular similarities with Sjögren's, but obviously a completely different cause. By subtracting COVID19-induced genes and gene sets from those we find in Sjögren's, we expect to be left with the truly Sjögren's-specific genes. We have done this type of analysis in lupus patients and the results were very exciting. Will Sjögren's be similar?

Continuing Research Grants from Prior Years

Seunghee Cha, DDS, PhD

University of Florida College of Dentistry

Project Title

Integrated Transcriptomic Profiling of Recurrent Parotitis in Pediatric Sjögren's for Assessment of Mitochondrial RNA Regulators

Abstract

Dr. Cha is working to uncover the gene signatures of juvenile Sjögren's immune cells with high-throughput sequencing. Preliminary data suggest that mitochondrial RNA may elicit the inflammatory signature in monocyte. Her team will determine how such altered gene signature of juvenile Sjögren's monocyte in the blood affects immune cell phenotype in the target tissue and hypothesize that robust inflammation in recurrent parotitis of juvenile Sjögren's presents more distinct mitochondrial RNA dysregulation compared to juvenile Sjögren's without recurrent parotitis or adult Sjögren's. Ultimately, their goal is to establish the scientific foundation for juvenile Sjögren's diagnostic criteria and targeted therapeutic interventions.



Addy Alt-Holland, PhD

Associate Professor, Tufts School of Dental Medicine, Department of Endodontics, Boston, MA

Project Title

Metabolic Profiles of Salivary and Epidermal Biomarkers for Sjögren's Diagnosis

Abstract

Dr. Alt-Holland is working to identify tear components that differentiate Sjögren's vs. non-Sjögren's dry eye. Such tear components can form the basis for a diagnostic test that helps clinicians detect Sjögren's earlier and manage treatment effectively to prevent development of serious complications.



Cintia S. de Paiva, MD, PhD

Associate Professor of Ophthalmology, Baylor College of Medicine - Ocular Surface Center, Department of Ophthalmology, Houston, TX

Project Title

Investigating Oral and Conjunctival Gene Transcriptome Signature in Sjögren's at the Single Cell Level

Abstract

Dr. de Paiva and her team believe that cells from the eye surface and mouth taken from patients with dry eye and dry mouth carry a distinct gene signature from patients with dry eye only and control subjects. They are using a novel technique that can identify the genes from the eye and the mouth at a single-cell level. Identification of a Sjögren's gene expression signature would provide relevant diagnostic markers that could be used in the future.



Sara S. McCoy, MD, PhD

Assistant Professor, University of Wisconsin School of Medicine and Public Health, Department of Medicine, Division of Rheumatology, Madison, WI

Project Title

Comprehensive profiling of Sjögren's autoantibodies identified from a novel whole peptidome array

Abstract

Dr. McCoy has identified hundreds of new autoantibodies by using cutting-edge whole peptidome array technology, which studies over 5.9 million peptides from every human protein. With this project, she is working to confirm these candidate autoantibodies, providing innumerable targets to both improve Sjögren's diagnosis and deepen our understanding of the causes of Sjögren's, ultimately driving development of new therapies. The results of this study have the potential to improve the lives of Sjögren's patients through advancements in diagnosis and treatment, current unmet needs in Sjögren's. ■



Do we have your current e-mail address?

If you want to receive all the latest updates from the Sjögren’s Foundation, then please make sure we have your most up-to-date e-mail address! The Foundation is starting to share more information via e-mail, from news about the Foundation and Sjögren’s, to information about the latest treatments and medicines, to local Support Group updates and more. So contact us at info@sjogrens.org to be certain we have your latest e-mail address in our database, and then keep an eye out in your Inbox for Sjögren’s news.

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Clinician's Corner: Conquering Sjögren's Genetics

Nancy Carteron MD FACR

*Rheumatologist, University of California, Berkeley and San Francisco,
Berkeley Optometry Sjögren's Clinic*

Does Sjögren's Run in Families?

Sjögren's, like most autoimmune diseases, can run in families. The clinical risk data is limited in Sjögren's, but one study of 12,754 persons in Taiwan diagnosed with Sjögren's found 105 siblings, children, or parents with Sjögren's. Thus, the prevalence of Sjögren's in a close relative was 12 times higher than the general population. Like most autoimmune diseases genetic risk factors account for roughly 30% of the overall risk of developing Sjögren's, along with environmental and gender factors, and a triggering event, for example a virus. Factors involved in gene regulation also play a role in developing the disease. The specific genes that confer risk in Sjögren's can vary by population. Genome Wide Association studies have been performed on patients of European, Han Chinese, and Asian descent. There are some similarities, but differences as well. Therefore, it is important to interpret the published data that we do have in the context of the population and geography of where the study was performed. The data may or may not be relevant to your family. Even less is known about the familial risk of Sjögren's in the setting of another autoimmune disease, but the risk for autoimmunity in general is increased.

Both the innate immune response, immediate to ward off an infection, and the adaptive immune response which involves long-lasting (memory) immune response are reflected in the Sjögren's specific genes identified to date. Immune response genes have the highest density on the X-chromosome. Females carry 2 copies of the X-chromosome (XX) compared to one

copy in males (XY), and the diversity of immune genes may contribute to immune dysregulation. Other factors may activate the innate immune system, like viral reactivation and tissue damage, leading to increased type 1 interferon production which can fuel inflammation and autoimmunity.

Research on the genetics and immune responses in Sjögren's continue to further understanding of the immune dysregulation in the disease, and will guide strategies to regain immune balance.

If my family member has Sjögren's, should I get tested?

Not under most circumstances. Testing should be driven by the presence of symptoms that suggest an autoimmune disease, like Sjögren's. However, if one has symptoms such as joint pain, severe fatigue, dry eye, dry mouth, significant dental decay, vaginal dryness, interstitial cystitis, nerve pain, persistent salivary gland enlargement, premature menopause, or persistent low white blood count, the possibility of Sjögren's should be considered and appropriate consultation and testing performed.

The one situation where testing for Sjögren's is wise is prior to pregnancy to screen for the presence of the SSA (Ro) and/or SSB (La) autoantibody. These autoantibodies are associated with neonatal lupus and fetal heart block, and preventive strategies can minimize risk. Individual cases should be discussed with the primary treating physician, rheumatologist, and/or possibly a high-risk fetal medicine specialist. ■

Sjögren's Foundation's Top 5 Tips to control your Raynaud's Syndrome

Raynaud's Syndrome occurs in approximately 37% of patients with Sjögren's.

Raynaud's Syndrome (sometimes called Raynaud's phenomenon) is defined as repeated episodes of color changes in the fingers and/or toes with exposure to cold temperatures or during episodes of emotional stress. The color changes are due to a spasm of the blood vessels that feed the fingers and toes. The digits typically turn very white, then can take on a bluish color with prolonged exposure to the cold, and finally can turn very red as blood flow resumes.

Sjögren's Foundation's Top 5 Tips to control your Raynaud's Syndrome:

- If you have access to water when a flare starts, run warm water over your fingers and toes until skin color returns to normal.
- Do not smoke — this constricts the blood vessels that feed the hands and feet.
- Moisturize your hands and feet every day to prevent your skin from cracking.
- When your hands or feet start to feel cold, wiggle your fingers and toes, move your arms and legs around to get blood flowing, or put your hands under your armpits to warm them up.
- Talk to your doctor about your symptoms. Several medications can be used to help the vessels stay dilated, including a class of blood pressure medications called calcium channel blockers. Some medicines, such as beta blockers used for high blood pressure, may make Raynaud's worse.

These Tips are from the Sjögren's Foundation Patient Education Sheet: Raynaud's Syndrome. ■



WHITE
POOR BLOOD CIRCULATION



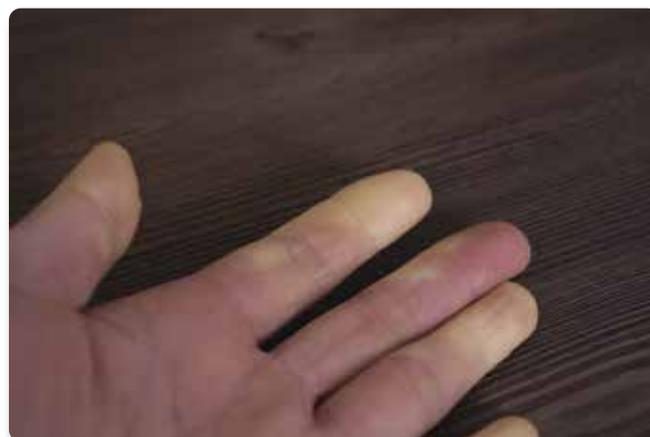
BLUE
LOW OXYGENATION



RED
BLOOD RETURNS AND MAY HURT



Top of hand experiencing Raynaud's Syndrome



Inside of hand experiencing Raynaud's Syndrome

Study sheds new light on genetic risk factors contributing to Sjögren's



Dr. Christopher Lessard

An international study, led by Dr. Christopher Lessard of the Oklahoma Medical Research Foundation, has published new research that nearly doubles the number of known genetic risk regions for Sjögren's to 22 total regions. Genetic risk regions are areas of DNA associated with increased risk of having a particular disease. Dr. Lessard shared that this is a critical development for understanding and treating Sjögren's. "Even though Sjögren's is more common than most other autoimmune diseases, our understanding of how genetics contribute to the disease has lagged far behind," said Dr. Lessard.

The study was supported by research grants from the National Institutes of Health (NIH) and involved scientists from 36 research institutions across 10 countries. Although more research is needed to

determine which genetic interactions contribute to Sjögren's, Dr. Lessard said, "We hope our improved understanding will result in earlier diagnosis and therapeutics that treat the disease itself, rather than simply treating the symptoms."

Dr. Lessard presented updates on his work at the recently held International Symposium on Sjögren's (ISSS). Dr. Lessard had four oral presentations and was an author on six different posters on genetics and epigenetics during the meeting. For more on the ISSS, see articles on pages 11 and 12 of this issue of *Conquering Sjögren's*.

Dr. Lessard is a former Sjögren's Foundation research grantee and has been researching Sjögren's for the past 15 years. To learn more about the Foundation's current grantees, see page 4 and 5. ■

Medicare and Medicaid Dental Coverage May Soon Be Available

The Centers for Medicare & Medicaid Services (CMS) has just opened the door for covering medically necessary dental care for Medicare patients! Because only a few conditions are mentioned and coverage for Sjögren's is not specifically stated, uncertainty exists as to whether dental care for dry mouth due to Sjögren's will be covered at this time. In addition, regional Medicare contractors will interpret the CMS ruling differently, and one's dentist must be enrolled in Medicare for coverage to be considered. However, the ruling is a major step forward for Sjögren's patients now that CMS officially recognizes that oral needs can be part of treating a medical condition.

The Sjögren's Foundation will continue to work with CMS to ensure dental care due to Sjögren's is specifically included in the future under Medicare rules. In the meantime, we encourage Sjögren's patients to ask their dentists when submitting expenses to insurance to use the new ICD-10 medical codes, which includes a listing under Sjögren's for dental involvement, and the new CMS ruling to request dental coverage and appeal coverage decisions when denied. Please let us know about your experience using these tools, so we can understand how they are working for Sjögren's patients and know best how to advocate for you. ■



Resource Order Form

	Non-Member	Member	Qty	Amount
The Sjögren's Book , Fifth Edition edited by Daniel J. Wallace, MD. The 2022 edition of the Sjögren's handbook has been completely revised and expanded with all new chapters and the latest information on Sjögren's.	\$38	\$32		
The Sjögren's Syndrome Survival Guide by Teri P. Rumpf, PhD, and Kathy Hammitt. A complete resource, providing medical information, research results, and treatment methods as well as the most effective and practical self-help strategies.	\$20	\$17		
The Immune System Recovery Plan: A Doctor's 4-Step Program to Treat Autoimmune Disease by Susan Blum, MD, MPH. This book shares Dr. Blum's four-step program to help autoimmune patients reverse their symptoms, heal their immune systems and prevent future illness.	\$25	\$22		
You Don't Look Sick! Living Well with Chronic Invisible Illness by Joy H. Selak, and Steven S. Overman MD. One woman's journey through the four stages of chronic illness: Getting Sick, Being Sick, Grief, and Acceptance and Living Well.	\$16	\$14		
Peripheral Neuropathy: When the Numbness, Weakness, and Pain Won't Stop by Norman Latov, MD, PhD. Peripheral neuropathy is a widespread disease, yet many people do not even realize they have it.	\$19	\$16		
You Can Cope with Peripheral Neuropathy: 365 Tips for Living a Full Life by Mims Cushing and Norman Latov, MD. A compendium of tips, techniques, and life-task shortcuts that will help everyone who lives with this painful condition.	\$19	\$16		
Healing Arthritis: Your 3-Step Guide to Conquering Arthritis Naturally by Susan S. Blum, MD, MPH (Author), Mark Hyman (Foreword).	\$24	\$20		
A Body Out of Balance by Ruth Fremes, MA, and Nancy Carteron, MD, FACR. A Sjögren's patient and a doctor offer their authoritative insight into one of the most common yet most misunderstood autoimmune disorders.	\$16	\$13		
Grain Brain: The Surprising Truth about Wheat, Carbs, and Sugar – Your Brain's Silent Killers by David Perlmutter, MD (author) and Kristin Loberg (contributor). A #1 New York Times bestseller – the devastating truth about the effects of wheat, sugar, and carbs on the brain, with a 4-week plan to achieve optimum health.	\$25	\$20		
How to Live Well with Chronic Pain and Illness – A Mindful Guide by Toni Bernhard. The book addresses challenges created from chronic illness to help readers make peace with a life turned upside down.	\$17	\$14		
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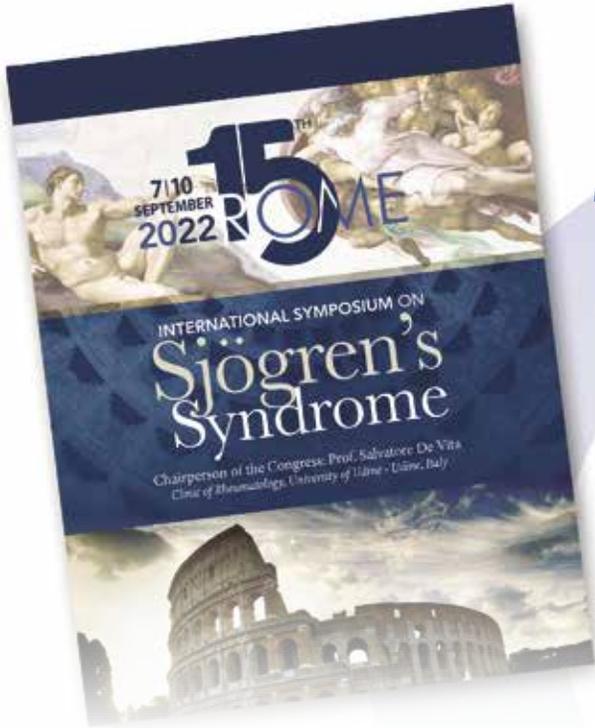
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The 15th International Symposium on Sjögren's

From September 7 to 10, 2022, hundreds of the world's leading experts in Sjögren's gathered in Rome, Italy, for the 15th International Symposium on Sjögren's (ISSS). Three staff represented the Foundation and participated in the symposium: Janet Church, CEO; Kathy Hammitt, MA, Vice President of Medical and Scientific Affairs; and Matt Makara, MPH, Sr. Director of Research & Scientific Affairs. In addition to the aforementioned staff, Foundation Board members and Foundation research grantees, past and present, were also in attendance and actively participated.

The meeting agenda was divided into themes to facilitate detailed discussion and share progress and future outlooks on a wide range of topics. Themes of the meeting included: evolving topics in Sjögren's pathogenesis, stratification, Sjögren's-related lymphoproliferation, the evaluation of Sjögren's, the disease biology and management of Sjögren's with other diseases, multi-disciplinary care, Sjögren's and COVID-19, Sjögren's therapy, health policies, and cooperative research.

The Foundation's Kathy Hammitt enthusiastically participated in two panel presentations during the meeting. The first, on Sjögren's-related nomenclature (see page 13 for more detail), and the second on patient needs and health policies. In her second presentation, Hammitt outlined recent Foundation activity and emphasized the need for increased collaboration and patient involvement to continue to move the field forward. This timely presentation was followed by overviews and updates on numerous international collaborations, including the new NIH Accelerated Medicines Partnership® Autoimmune and Immune-Mediated Diseases (AMP® AIM) Program (U.S.), the Big Data Consortium (Europe), PRECISESADS



Kathy Hammitt presenting at Symposium

(Europe), HarmonicSS (global), Necessity (Europe), and the Sjögren's Genetics Network (SGENE) global

In addition to the oral presentations and discussions, more than 150 scientific posters were submitted and accepted to the meeting, including three from the Foundation on topics that included perceptions and behaviors related to COVID-19, the occurrence and impact of neurological complications on quality of life in Sjögren's, and an update on the development of peripheral and autonomic clinical practice guidelines being led by the Foundation. During the poster sessions, attendees had the opportunity to connect with colleagues, old and new, and learn about and discuss a wide range of topics.

On behalf of the Foundation, we thank the organizers and all of our colleagues, domestic and international, for coming together and sharing their work, prioritizing patients, and moving forward with enthusiasm to help improve our understanding of the disease and our ability diagnose, manage and treat Sjögren's patients everywhere.

This meeting was last held in Washington DC in 2018. The next iteration of this meeting will take place in the Netherlands in 2024. ■

Sjögren's Foundation In Action!

International Symposium on Sjögren's and Nomenclature Initiative Highlights

by Janet Church

I was very excited to attend my first International Symposium on Sjögren's held in Rome. The specifics of the conference are stated in the earlier article on page 11, but I also wanted to share what I thought were key conference highlights from a patient's perspective as well as information on the nomenclature initiative presented by Kathy Hammitt of the Foundation.

Conference Highlights

There were many presentations and posters at the conference and all for a scientific audience. Much of the data was very deep research and science that has yet to be applied, but new discoveries are exciting and new research and collaborations will truly make a difference in what we know about Sjögren's. Here are my highlights:

- New research is shaping our knowledge of Sjögren's and how patients are evaluated and understood. For example, research was presented on the discovery of novel antibodies in seronegative patients. A separate research project showed that seronegative patients have a higher pain level. And we are learning more about the differences between patients who present primarily with dryness symptoms and fatigue from those who have organ involvement and other systemic symptoms in addition to dryness.
- Additional genes related to Sjögren's have been discovered. We do not know what this means yet, but the discovery is exciting nonetheless.
- Researchers at Tufts have identified a salivary exosomal RNA signature which could be a new biomarker in Sjögren's.
- There have been advancements in salivary gland ultrasound use that could replace lip biopsies for diagnosis and determining disease progression.



Janet brings Team Sjögren's to the Colosseum

This would be a great alternative to conducting lip biopsies!

- Other research addressed fatigue and pain and their association with Sjögren's, two symptoms that can be very different for each patient, yet we know most of us have.
- There was also a lot of discussion on the tools that clinicians and researchers use to measure the degree of disease activity in a patient – such as ESSDAI, ESSPRI, CRESS, and STAR. The use of these tools also has implications for the process by which clinical trials are managed so we can get new therapies on the market.
- More highlights from the conference include the rise of new collaborations and partnerships, and exciting work between doctors and engineers using artificial intelligence (AI). The use of AI technology has the potential to expedite diagnosis and patient stratification to determine the best clinical approach to treatment and care, and to accelerate other findings with greater accuracy. Interest in research continues to expand and global collaborations have taken shape – both of which are contributing to rapid advancements in the field.

This is an exciting time for new discoveries and partnerships to better understand and change the face of Sjögren's! I can't wait to learn more as these research projects progress.

The Nomenclature Initiative was another key part of the conference. This initiative was launched by the Sjögren's Foundation and supported by Dr. Alan Baer, the Foundation's Chair of Medical and Scientific Affairs and Director of the Sjögren's Clinic at Johns

Hopkins, and Dr. Manuel Ramos-Casals in Spain. Our Vice President of Medical and Scientific Affairs, Kathy Hammitt, gave a presentation on the patient voice around nomenclature and shared the results of a global survey taken by Sjögren's patients and clinicians on this topic.

Nomenclature has a profound effect on how patients perceive themselves and how others perceive Sjögren's disease and Sjögren's patients. For many patients, the use of words such as "syndrome" and "secondary" feels insufficient and lessens other people's understanding of the severity and devastating consequences of this disease. This initiative is being conducted using a formal process, which started with literature reviews of terms used in scientific writings and research around the world to assess trends. We then looked at other diseases that have changed their name. Then, in coordination with other patient advocacy groups throughout the world the Foundation launched a survey for Sjögren's patients while Drs. Baer and Ramos-Casals surveyed their clinical colleagues worldwide. We had a short timeframe for the responses and were amazed and grateful that 1,642 patients responded from 24 countries. Additionally, we received responses from 90 clinicians across 28 countries.

The key questions and responses were:

Do you agree with maintaining the eponym Sjögren or Sjögren's?

The vast majority of Sjögren's patients and clinicians strongly agreed with retaining the term "Sjögren" or "Sjögren's."

Do you agree with maintaining the term "syndrome"?

There was little patient support for use of the word "syndrome" – we also received more than one thousand patient comments on this term, with most viewing the term negatively.

Respondent comments from the 2022 Nomenclature Initiative Survey:

"Syndrome sounds much more benign than what I experience as a Sjögren's patient."

"Syndrome signifies to most persons not familiar with our issues that it is not as important or as debilitating as a disease."

"When I say the words Sjögren's syndrome. I always get 'well that's not so bad, it's just a syndrome, not a disease.'"

"As a physician with this disease, I agree that syndrome is misleading ... we have learned enough to see this is obviously a disease, and a serious one at that."

continued page 16 ▼

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Season of Giving

It is truly an exciting time in Sjögren's. 2022 has seen amazing growth and advancements in several key areas including research and clinical trials, patient support, and provider education. The Sjögren's Foundation is incredibly proud of all the many successes and accomplishments achieved in the past year. Additionally, we are humbled and proud to continue to advocate in honor of all Sjögren's patients and to play a key role in delivering support and services to patients in need across the country.

This past year, the Foundation was saddened to lose our beloved founder Elaine Harris, a true advocate for Sjögren's patients. But her mantra "founded by a patient, for patients" remains at the center of what we do by ensuring that the patient, and the patient voice, is never lost in our efforts. And we will carry on her legacy by continuing to always put the patient first.

We are truly grateful that you share our passion and vision to strengthen our Sjögren's community and to conquer the complexities of this complex and serious disease. For giving your time and energy and sharing our passion and vision to strengthen our Sjögren's community and conquer the complexities of this complex and serious disease.

As 2022 comes to a close, we reflect on a dynamic year in Sjögren's and excitingly look ahead to the progress and advancements that the future holds. While we continue to make great strides, there is even more work to be done which is why we are asking you for your support as we eagerly approach a new year. Please consider giving a year-end donation and together, we can continue to make a difference for all those living with Sjögren's.

Wishing you a joyous holiday season and happy New Year!



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- Please send me information about listing the Sjögren's Foundation in my will.

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Increase in Clinical Trials Requires Increase in Patient Participation!

We are at a very exciting time for Sjögren's! In fact, here at the Foundation, we believe we are at that tipping point where knowledge gained from research is finally leading to greater interest and progress in developing new therapies. With therapies poised in the next few years to come to market specifically for Sjögren's for the first time ever, we will experience a substantial change in what we know about Sjögren's and how patients' lives can be improved for the better.

There are now thirteen (13) companies with twenty-one (21) potential systemic therapies, specifically for Sjögren's, in clinical trial or getting ready to begin their clinical trial. This is an impressive commitment to patients because the companies must first believe that they have a scientific approach that can benefit Sjögren's patients, and then they must commit to the process and investment for years to (hopefully) bring that therapy to market.

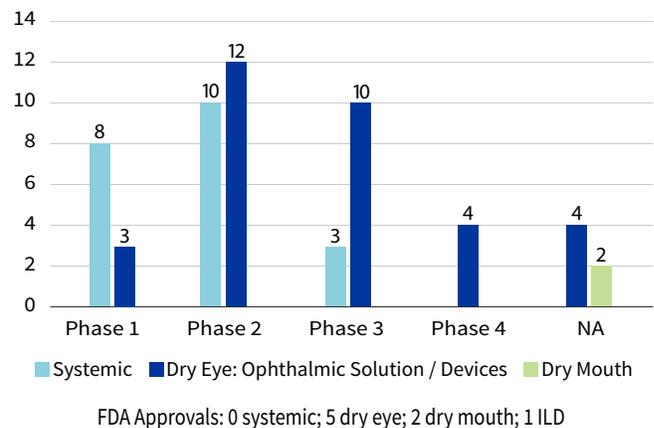
We are fortunate that so many companies are making that commitment to patients! We are also lucky that companies have therapies in the pipeline that address different biological pathways of the disease, which will allow options for the patient. Sjögren's lives within each patient differently, so it is anticipated that some drugs will work better for some patients whereas a different drug that addresses a different pathway will work better for other patients.

Clinical Trials in Phase 2 and Phase 3

There are twenty-one (21) systemic therapies in clinical trial: eight (8) in Phase 1, ten (10) in Phase 2 and three (3) in or coming into Phase 3 in the new year. There are also thirty-three (33) trials occurring in different phases for dry eye and Ophthalmic solutions and devices. And two very interesting dry mouth therapies in trial. If you are not able or do not

qualify for a systemic trial, perhaps a dry eye or dry mouth trial is a good option for you!

Current Clinical Trials



A Significant Challenge

We need patients to call about the clinical trials listed on our website! With all of these clinical trials occurring at the same time, there is a challenge to get enough patients enrolled in each trial. Many of you have seen multiple emails from the Foundation announcing a trial or have seen our social media posts. These emails and posts are all different companies enrolling for different trials. So, each time we release an announcement for a trial, we urge you to look into that trial and see if there is a location near you enrolling. Clinical trial sites are generally located in major cities in the U.S., but even if you live a fair distance away, do call the nearest site as some companies are making accommodations for travel and are listening to what you might need in order to participate.

“Nomenclature” *continued from page 13* ▼

However, both patients and clinicians supported the use of the term “disease,” as it properly connotes the seriousness and legitimacy of Sjögren’s.

Do you agree to maintaining use of the term a) “primary” b) “secondary”? Do you agree with changing to the term c) “associated”?

With respect to some of the other terminology addressed by this survey, patients very much disagree with using the terms “primary” and “secondary.” A slight majority of clinicians want to drop use of the word “primary,” whereas a vast majority of clinicians want to drop the use of “secondary.” Although patients generally registered as neutral on the term “associated,” most clinicians expressed support for use of this term, and there was active discussion

around this word at the conference. Here, patient advocacy groups added comment at the conference that this seemed to be unnecessary and might still present Sjögren’s as the “secondary” disease: You have Sjögren’s and RA...or Lupus and Sjögren’s.

What’s next?

The next steps for this initiative will include a second survey of patients and clinicians, followed by more analyses and presentation of results for submission to journals. Any nomenclature changes will take time, but the entire Sjögren’s community around the world agrees that it is time for this language to change! The Foundation is excited to take part in leading this change and will continue to share our progress with you. ■

“Clinical Trials” *continued from page 15* ▼

If you are curious about what it means to take part in a clinical trial, please call the nearest trial site to ask questions. Calling does show the companies that there is interest in these therapies and simply calling does not mean that you are committing to enrollment.

Hope for our future

As a patient living with Sjögren’s, you are very aware of how this disease has impacted your life. These new therapies bring real hope to all patients that soon every patient living with Sjögren’s will have a higher quality life than they have today. And as new therapies come to market, companies will advertise these therapies and bring greater awareness to the general public about Sjögren’s disease, helping those millions of people who are currently misdiagnosed or undiagnosed get the help they need to manage this serious and complex disease. New therapies also raise awareness on the part of healthcare providers, giving them new tools for treating their patients and increasing their recognition that Sjögren’s is a serious disease that warrants treatment.

We just need more patients to enroll in clinical trials to make this happen!

Learn more at <https://www.sjogrens.org/living-with-sjogrens/clinical-trials>. On this page, we have a video by Dr. Herb Baraf on “Clinical Trials: What Every Patient Should Know” that guides patients considering engaging in a clinical trial. The same page offers links to more information on resources on clinical trials and a list of trials by state. ■

What happens in each Phase of a Clinical Trial?**Phase 1**

- The first testing of a drug in humans
- Conducted with a small number of volunteers (20-100 participants)
- Purpose is to determine how the body handles a drug – how it is metabolized and eliminated
- Screens for adverse effects

Phase 2

- Small-scale program in up to a few hundred patients with the targeted disease
- Purpose is to evaluate efficacy and side effects and to determine ideal dosing
- About 33% of drugs studied in phase 2 go on to the next phase

Phase 3

- Larger number of patients with disease studied (from 200 to >3,000); Primary concern is effectiveness and safety
- About 25-30% of new treatments are eventually approved by the FDA and come to market

Phase 4

- These studies are usually performed after a drug has been approved
- Often mandated by the FDA and agreed to by the sponsor (drug company) as a condition of drug approval
- Large-scale program evaluating several thousand volunteers with focus on safety



IN MEMORIAM

In Memory of Cheryl Wilcut
Sharon Benner

In Memory of Elaine Harris
Karen Marston

In Memory of Ella Sisler
Darla Rae
Joe Sisler

In Memory of James Coxon
Eve Overchuk

In Memory of Karen Caron
Elaine Gingerella

In Memory of Louise Calaway
Laura Stone

Joel Fritsche and Lynne Parmenter
Sharon Ramsey
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**In Memory of
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Maria Fotopoulos

IN HONOR

In Honor of Adrienne Jones
Ariel Weber

In Honor of Ann Poulter
Sam Fisher

**In Honor of
Benner-Cornelison Wedding**
Danielle Phillips

In Honor of Cheryl Quasny
Union Pacific

In Honor of Jennifer Bromberg
Robert Wald

In Honor of Liz Perry
Don Perry

In Honor of Monica Dougherty
Robert French & Pamela Pletcher

In Honor of Morgan Cornelison
Janet Perkowski

**In Honor of
Ni-Asia/Ricky Wedding Guests**
Ni-Asia Twiggs



2023 Virtual National Patient Conference

*Conquering
Sjögren's Together*

April 21 – 22, 2023

***Save The Date For The 2023
National Patient Conference!***

As the new year approaches and you begin making plans, mark your calendars for the 2023 Sjögren's Foundation National Patient Conference! This two-day, virtual event will be held on April 21 and 22, 2023. As in the past, you can expect a fantastic lineup of presenters sharing pertinent Sjögren's information that is designed to help you better understand and manage your symptoms. We look forward to having you join us for this informative educational experience!

Update on the FNIH-NIH AMP[®] AIM Research Program



The Transformative Partnership to Identify and Map Key Biological Pathways That Drive Autoimmune and Immune-Mediated Diseases

In May 2021, the Sjögren's Foundation committed to a major research project with the Foundation for the National Institutes of Health (FNIH) and the National Institutes of Health (NIH) to further understand autoimmune diseases. Our CEO, Janet Church, has spoken about the AMP[®] AIM project often as the Foundation invested \$300,000 for the first three years and will invest an additional \$200,000 for years four and five – our largest single research investment to date. This investment level places the Foundation on the Steering Committee as equal partners to other large patient advocacy organizations and the nine industry corporations. Kathy Hammitt, VP of Medical and Scientific Affairs for the Foundation and Dr. Steven E. Carsons, a member of our Medical and Scientific Advisory Board, represent the Foundation on the Steering Committee.

The purpose of the Accelerating Medicines Partnership[®] Autoimmune and Immune-Mediated Diseases (AMP[®] AIM) Program is to investigate how cells of the immune system interact in tissue to drive inflammation and autoimmune disease. The key goal of the program is to advance our understanding of key disease pathways using new tools to map, in three dimensions, how cell types, cell states, and cell-to-cell interactions network to cause inflammation, abnormal function, and tissue injury. The resulting data will accelerate our understanding of the fundamental mechanisms and causes of autoimmune disease, allow more informed selection of patients for clinical trials, and generate new targets for drug development.

The AMP[®] AIM program is an extended phase of the AMP RA/SLE Program which has been conducted over the past seven years. This program has advanced new technologies and analytical methods using biopsy

and blood samples of diseased tissue from major organs such as the kidney in lupus and the joints in arthritis. These technologies allow us to discover novel cell populations and pathways that could provide promising new targets for drug development. AMP[®] AIM will extend this model to the study of additional diseases, including psoriasis/psoriatic arthritis and Sjögren's disease. AMP AIM brings together the resources of 19 partner organizations spanning the public, private, and nonprofit sectors, with combined commitments totaling over \$58.5 million. The FNIH will provide program and project management for the effort over the next five years.

The Sjögren's grant of \$900,000 was awarded to a team of PIs (Principal Investigators) titling themselves the Sjögren Team for Accelerating Medicines Partnership (STAMP):

- Dr. Caroline Shiboski (UCSF)
- Dr. Alan Baer (Johns Hopkins)
- Dr. Darise Farris (OMRF)
- Dr. Blake Warner (NIDCR)
- Additional team members hail from UC Berkeley, NYU Langone, and HSS
- Our own Kathy Hammitt is also on the STAMP team ensuring the patient voice is always represented

There are also STAMP subcommittees that include:

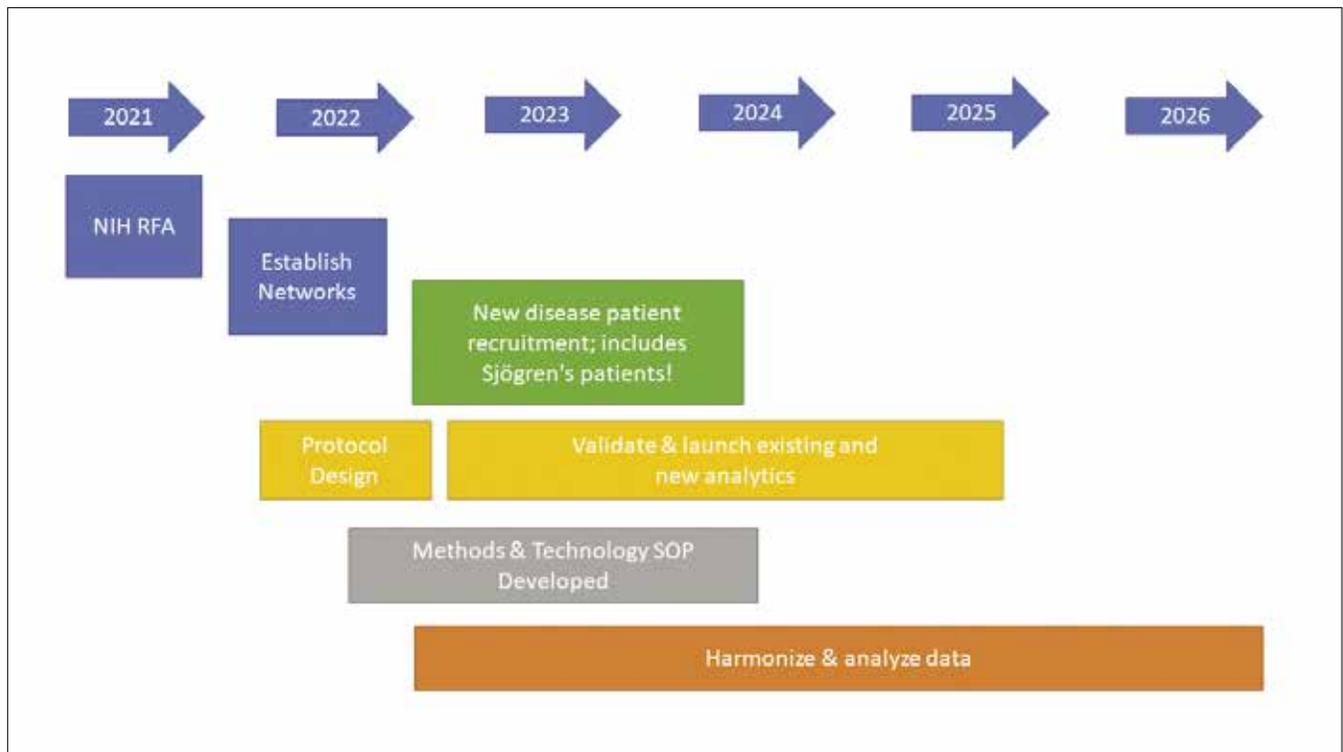
- Rheumatology (including Dr. Alan Baer and Dr. Nancy Carteron)
- Ophthalmology (including Dr. Esen Akpek and Dr. Nancy McNamara)
- Oral Medicine (including Dr. Ava Wu)
- Otolaryngology
- Oral Pathology

- Recruitment and Patient Perspective (Kathy Hammitt of the Foundation as Chair)

This team will dive deeply into understanding Sjögren's, as the other teams do the same for their disease. There will also be a number of projects across the four diseases to analyze what is similar and what is distinct between the diseases.

AMP® AIM is the most significant research to date on Sjögren's disease and on how four autoimmune diseases relate to one another. We expect to see amazing insights from the research that could change the way we think about Sjögren's, the way we diagnose patients, and how to develop therapies that can work for all patients. ■

The AMP®AIM Timeline for Scientific Milestones Over Next 5 Years



Janet's Quote for FNIH Formal Press Release

“Sjögren’s is a systemic autoimmune disease that is frequently misunderstood and underdiagnosed. We are extremely proud to join the AMP AIM project as a Steering Committee member alongside the NIH, other disease advocacy organizations and pharmaceutical companies. AMP AIM offers a new way to tackle the formidable barriers that have prevented us from fully understanding Sjögren’s and will potentially uncover mysteries so we can better diagnose and treat Sjögren’s patients in the future.”

*Janet Church
President and CEO
Sjögren’s Foundation*



Conquering Sjögren's

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