Medical & Scientific Initiatives
Professional Education & Awareness

- Sjögren’s Quarterly
- Awareness Ambassadors
- CME Programming
- Professional Conferences
- National Coalitions, Boards, and Other Groups
- International Initiatives and Collaborations
Town Hall Agenda

• Clinical Trials Consortium
• ICD Coding Change
• Clinical Practice Guidelines
• Research Funding & Support
Why form a Clinical Trials Consortium?

- Patients need a systemic therapy for Sjögren's, and we recognized that industry was not interested in developing one!

Foundation’s Response:

- Organized an expert, international group to identify barriers to successful clinical trials and strategize together about how to overcome them.
  - Companies fear entering Sjögren's, because no clear path has been established for FDA approval
  - Critical elements are missing for successful clinical trials
**International Clinical Trials Consortium**

**Actions Taken:**

- Launched a dialogue with Industry and Key Opinion Leaders in Sjögren’s

- Led international community to develop one set of criteria to identify Sjögren’s patients for use in clinical trials

- Forged a relationship with the U.S. Food & Drug Administration (FDA)

- Created an online training program on Sjögren’s outcome measures (Sjögren’s Training and Education Platform, or STEP)

- Encourage and support initiatives to identify better outcome measures and find new biomarkers
Next Steps:

- Keep regular discussions going with industry and international leaders in Sjögren’s to keep everyone engaged and focused on successful clinical trials.
- Continue to focus on key questions in clinical trial design.
- Expand STEP to include multiple outcome measures and testing done in Sjögren’s.
- Take leadership roles on new outcome measures (OMERACT and NECESSITY).
- Partner with the Foundation for the NIH (FNIH) on finding new biomarkers.
- Match clinical trial sites with industry needs.
Change the ICD Code!

What is the ICD-10 Code?
- A coding system for diagnosis used around the world by healthcare providers

SUCCESS!
- ICD-10 Code changes will take effect in October 2020
- Changes will continue in the next update for the ICD-11 Code

The CDC and American College of Rheumatology (ACR) joined us in this effort.
Change the ICD Code!

**Why change the ICD Coding for Sjögren’s?**

- **There was no dedicated code for Sjögren’s!** We currently fall under “SICCA.”
  - Sicca is a symptom and not a disease
  - Sicca is not Sjögren’s! Sicca simply means dryness and can result from multiple causes
- The current coding is **inaccurate** and doesn’t reflect the disease.
- Improper coding **contributes to delayed diagnosis and misdiagnosis.**
- Adding manifestations to the list **opens physicians’ eyes** to the fact that these occur in Sjögren’s and they need to look for them!
- Proper coding will **help researchers** and **aid in understanding the true prevalence and health-related costs of Sjögren's.**
Change the ICD Code!

- **Sjögren’s is now the main heading!**
- **7 new complications were added, with checklist now including:**
  - Inflammatory arthritis
  - Myopathy (muscle pain)
  - Peripheral nervous system involvement
  - Gastrointestinal involvement
  - Lung involvement
  - Tubulo-interstitial nephropathy (kidney disease)
  - Glomerular disease (kidney disease)
  - Central nervous system involvement
  - Vasculitis
  - Ocular involvement (Keratoconjunctivitis or KCS)
  - Dental involvement
  - Other organ involvement
Clinical Practice Guidelines

Why Clinical Practice Guidelines?

- **Patients** need expert, consistent care

- **Physicians** need to know how to best manage and treat patients. They need to understand Sjögren’s, take it seriously, and appreciate the potential severity and all the ways it can affect the body

- **Insurance companies** need published guidance for reimbursement

- **Researchers** need research gaps identified

- **Multiple medical specialists** need to recognize Sjögren’s
Why do Guidelines take so long?

- To be used by the medical community, guideline development requires a highly rigorous, well-defined, complicated, unbiased, and transparent process.

- This takes many, many hours, over a long period of time, gathering the right people, and is a huge effort on the part of Foundation staff and the healthcare providers who voluntarily contribute their time.
Clinical Practice Guidelines

Pulmonary Guidelines just completed!

Journal submission contained:

- Guidance on screening, upper and lower airway disorders, interstitial lung disease, and lymphoproliferative disease
- 51 Recommendations with a Clinical Rationale for each
- 5 Tables and 3 Figures to guide the physician
- Online Supplementary Materials with 15 Appendices totaling 128 pages
- 164 References
Clinical Practice Guidelines

Completed Guidelines:
- Fatigue
- Inflammatory Musculoskeletal Pain
- Use of Biologics
- Caries Prevention
- Ocular Management & Treatment
- Pulmonary – submitted for publication

Next Steps? Complete Guidelines on:
- Peripheral Neuropathy (incl autonomic nervous system)
- Central Nervous System
- Lymphoma
- Vasculitis
- Gastrointestinal complications
- Gynecological complications
- Caries Restoration; Mucosal Management & Symptom Relief
- Use of Secretagogues; Parotid Gland Swelling
Research Program

To increase interest in Sjögren’s research and accelerate scientific and clinical knowledge about Sjögren's, the Foundation:

• Awards Sjögren’s Foundation Research Grants
• Recognizes junior investigators in rheumatology by providing Sjögren’s Foundation Abstract Travel Awards
• Encourages greater focus on Sjögren’s by the NIH through its research and grants
• Brings researchers together to spark enthusiasm and collaboration
• Executes and analyzes surveys that add to our knowledge about Sjögren’s and catalyzes greater interest by industry
And we are always ready to take action on issues and opportunities as they arise!

For example:
COVID-19 and the many needs of our patients, including addressing the hydroxychloroquine/Plaquenil® shortage for Sjögren’s patients
Our Vision

To create a community where patients, healthcare professionals, and researchers, come together to conquer the complexities of Sjogren’s!