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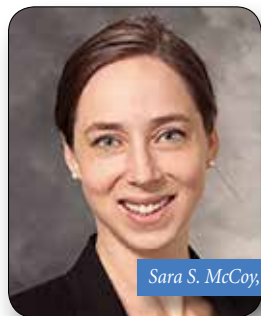
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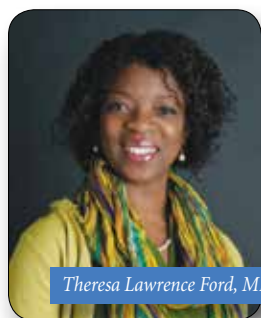
The Need, Process and Barriers to Opening a Sjögren's Clinic

Sjögren's is a chronic multi-organ systemic autoimmune disease frequently encountered in daily rheumatology practice. The diagnosis and treatment of this disease demonstrates the need for multi-specialty collaboration. The 2016 American College of Rheumatology/European League Against Rheumatism classification criteria for Sjögren's reflects the multi-specialty nature of the disease through inclusion of the minor salivary gland biopsy, Schirmer's test, unstimulated salivary flow rate, ocular staining score, and serum anti-SSA antibody (readily available in most settings).¹

Current Clinical Practice

For the diagnosis of Sjögren's, at least four subspecialists might be involved – otolaryngology, ophthalmology, pathology and rheumatology. The minor salivary gland biopsy

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Chair, SSF Clinical Trials Consortium;
Chair, SSF Medical and Scientific Advisory Board; and CEO and Medical Director, North Georgia Rheumatology Group, PC, Lawrenceville, GA

SSF Clinical Trials Consortium: An Update

A lot has happened since the last time I wrote about the Sjögren's Syndrome Foundation (SSF) Clinical Trials Consortium (CTC) in the Summer 2017 issue of *Sjögren's Quarterly*. Before I detail what's taken place and where we're heading, I feel it's important to provide a reminder of, or introduction to, the groups purpose for those who may not be familiar.

First convened in 2014, the CTC is an international initiative whose mission is to increase the availability and accessibility of therapies for treating Sjögren's. Since its inception, the CTC has focused on the following goals in pursuit of accomplishing our mission:

- To support and promote objectives that facilitate the design of clinical trials;
- To increase industry partnerships with the SSF;
- To engage in dialogue with government agencies that

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oversee therapy approval (i.e., the U.S. Food and Drug Administration [FDA] and the European Medicines Agency [EMA]).

Recent Discussions

In October 2018, the CTC leveraged the opportunity to meet while many of our members and others interested in Sjögren's clinical trials were in Chicago, IL, for the American College of Rheumatology's 2018 Annual Meeting. Here, the group of nearly 60 individuals, representing industry and both U.S.-based and international institutions, focused the discussion on considerations for enrolling more Sjögren's patients into clinical trials while ensuring an effective design is maintained.

This six-part discussion was led by a variety of leaders in the field and touched on an array of important questions that need to be addressed, including:

1. Whether patients with low ESSDAI activity/less severe disease should be considered for trial inclusion
2. Whether we're too restrictive with patient classification criteria for trial enrollment
3. Whether we should include all Sjögren's patients in trials, regardless of whether they have another major rheumatic disease
4. Whether we should allow patients to remain on standard of care therapy or concomitant drugs
5. Whether patients who have previously used biologics or similar therapies should be included
6. Whether we should target the full systemic disease or a small, defined subset of the disease
7. Whether demographic variables, including duration of disease, age, race and ethnicity should be considered

The conversations around these questions sparked important dialogue that has since continued as we work together to determine how to ensure adequate enrollment in well-designed trials for Sjögren's.

Most recently, the CTC met in Boston, MA, in early April. This meeting brought together a range of industry partners and colleagues, both new and old. Here, additional feedback was gathered on the aforementioned questions related to Sjögren's and clinical trials in addition to an industry presentation on critical lessons learned from a recent trial. Importantly, Chiara Baldini, MD, PhD, provided an update on biomarkers and Sjögren's, which provided key insights into what's taking place in both diagnostic and prognostic biomarkers in health care and research. This was followed by a presentation from the Foundation for the NIH Biomarkers Consortium, which is working closely with the SSF to propel identification of biomarkers in Sjögren's forward.

A key reason for holding this meeting was to discuss a variety of new initiatives and partnerships on outcome

measures that are now underway, or under consideration, for Sjögren's. To begin, Fai Ng, MD, PhD, presented and answered questions on the NECESSITY project (New Clinical Endpoints in primary Sjögren's Syndrome: an Interventional Trial based on stratifying patients), followed by a presentation on OMERACT (Outcome Measures in Rheumatology) by myself, and finally, a presentation on NIH PROMIS® (Patient-Reported Outcomes Measurement Information System) by Daniel Wallace, MD.

The CTC recognized the importance of not duplicating efforts, rather, we want to ensure that the groups help strengthen the work of one-another while independently advancing the field. As these initiatives are just now getting underway there will be more to share and report on as the work progresses.

Consortium Initiatives



The Foundation is excited to announce that the first phase of the STEP (Sjögren's Training and Educational Platform) initiative has launched and is now available!

For those unfamiliar, STEP is an online training platform designed to coordinate training and testing for clinical instruments used in the assessment of Sjögren's patients for medical professionals in the research community. This initiative was developed in response to an identified need for expert and consistent training on outcome measures and clinical testing used for clinical trials in Sjögren's and education for clinicians across specialties who manage and treat patients using these outcome measures. Tools, including video, demonstrating how to perform Sjögren's-specific tests are also being planned for inclusion.

Our hope, and belief, is that this new platform will encourage a greater interest within industry for developing new Sjögren's therapies and help facilitate the conduction of high-quality clinical trials. The consistency in training and subsequent data collection made possible through the utilization of STEP is critical to allowing data to be compared between centers and trials to determine if a therapy is truly safe and effective.

Companies who are interested in utilizing the STEP program can contact the Foundation to learn more.

ICD-10 Code

As was first mentioned in the Fall 2018 issue of *Sjögren's Quarterly*, a concerted effort informed by a team of multi-disciplinary experts is underway to

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change the current ICD-10 code for Sjögren's to be more representative of the disease. Why is this important you might ask? Issues with coding can have negative consequences for all stakeholders – patients, clinicians, researchers and insurers included.

As of this writing, two ICD-10 Coordination and Maintenance Committee Meetings have been held at the U.S. Centers for Medicare and Medicaid Services in which Sjögren's was a topic of presentation. At the first meeting, in September, 2018, Alan Baer, MD, presented an overview of Sjögren's and provided expertly stated reasoning and rationale for why changes to the ICD-10 code for Sjögren's were needed. Here, a representative from the Centers for Disease Control and Prevention (CDC) provided additional information related to the specifics of the actual tabular changes being requested. A second meeting was held in March 2019, in which a CDC representative again provided an overview for the requested

changes. Katherine Hammitt, SSF Vice President of Medical and Scientific Affairs, was on hand and responded to the few questions from the audience that were raised.

While we are still awaiting a decision on this important work, these meetings have been informative and encouraging for the future of Sjögren's. Once a decision has been made, a more in-depth article on this effort will be published in a future issue of *Sjögren's Quarterly*.

Looking Forward

There's a lot happening and a lot to be excited about in the world of Sjögren's right now. We will continue to work, collaborate and expand our reach to establish and foster new partnerships to facilitate the effective design of clinical trials for Sjögren's. On behalf of the foundation and myself, I want to thank all who have been involved and supported the work of this consortium in these important efforts and restate my excitement for what the future holds. ■



Theresa Lawrence Ford, MD (center), with CTC members Chiara Baldini, MD, PhD (Italy, far left); Katherine Hammitt, MA (United States, second from left); Stephan Gandola, MD (Switzerland, second from right); Benjamin Fisher, MD (United Kingdom, far right).



To learn more about the Sjögren's Syndrome Foundation Clinical Trials Consortium please visit www.sjogrens.org.