SJÖGREN'S INTERNATIONAL COLLABORATIVE CLINICAL ALLIANCE (SICCA) BIOREPOSITORY AND DATA REGISTRY
BACKGROUND AND PURPOSE

BACKGROUND

SICCA was funded from 2003 - 2013 by the National Institute of Dental and Craniofacial Research to:

- Develop new classification criteria for Sjogren's syndrome (SS)
- Better characterize the SS phenotype and genotype
- Establish an SS data and specimen repository to support future research, including genetic studies, by investigators worldwide

Clinical data and specimens were collected from 9 participating research sites

	N enrolled at baseline:
• University of Buenos Aires, German Hospital, Argentina	441
• Peking Union Medical Collage Hospital, China	333
• Copenhagen University Hospital, Denmark	610
• Kanazawa Medical University, Japan	368
• Aravind Eye Hospital, Madurai India	161
• King's College London, United Kingdom	312
• University of California, San Francisco, CA USA	718
• University of Pennsylvania, Philadelphia, PA USA	266
• Johns Hopkins, Baltimore, MD USA	305
Total enrolled at baseline:	**3514**

Each site included at least one rheumatologist, ophthalmologist, and one oral medicine/oral pathology specialist.

Enrollment Criteria for SICCA Cohort

- 21 years or older **and**
- Complaint of dry eyes or dry mouth, **or**
- Have a previous suspicion or diagnosis of SS, **or**
- Have bilateral salivary gland enlargement, **or**
- Have recent increase in dental caries, **or**
- Have elevated: anti-nuclear antibodies (ANA) or rheumatoid factor (RF) or anti-SSA/anti-SSB, **or**
- Have a diagnosis of rheumatoid arthritis (RA) or systemic lupus erythematosus (SLE) **and** any of the above.

In 2012 the classification criteria for SS, developed by the SICCA study investigators, were provisionally* approved by the American College of Rheumatology and are as follows:

A patient who meets 2 or more of the following criteria, is classified as having Sjögren's Syndrome (SS):

- Positive serum anti-SSA and/or anti-SSB or: positive RF *and* ANA e 1:320
- Ocular staining score (OSS) e 3
- Presence of focal lymphocytic sialadenitis (FLS) with a focus score (FS) e 1 focus/4mm2 in labial salivary gland biopsies

*****_This criteria set has been approved by the American College of Rheumatology (ACR) Board of Directors as Provisional. This signifies that the criteria set has been quantitatively validated using patient data, but it has not undergone validation based on an external data set. All ACR-approved criteria sets are expected to undergo intermittent updates._

Baseline SS status in SICCA Cohort

SS	1578 (46%)
Non-SS*	1831 (54%)

(*including 588 "controls" with no positive objective tests)

PURPOSE

To disseminate clinical data and specimens collected from subjects enrolled in the Sjögren's International Collaborative Clinical Alliance (SICCA) study to researchers who are interested in basic and clinical studies on this disease. To provide scientific advice regarding study design in order to optimize use of the specimens and data prior to distributing these specimens and the accompanying clinical data to qualified investigators.