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**

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<tr>
<td>SS</td>
<td>1578 (46%)</td>
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<tr>
<td>Non-SS*</td>
<td>1831 (54%)</td>
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(*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.