



2024 Dynamic Grant

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Project Title: Development of a Core Outcomes Set of Domains for Sjögren's Disease

Sjögren's disease (SjD) has limited precise and reliable patient-reported outcome measures (PROs) to understand health related quality of life (HRQoL) from the patient perspective. SjD highly impacts HRQoL because of symptoms such as pain and fatigue, which drive patient disability, loss of work productivity, and healthcare utilization. The overall objectives are to identify SjD domains that are important to all relevant SjD stakeholders and generate a core outcome domain set. The rationale is that through the rigorous methodologic OMERACT framework, we will define key disease domains and core set measures to generate optimal measurement tools for clinical trials. The central hypothesis will be tested by three specific aims: 1) Generate a comprehensive list of important domains in SjD for each key aspect of disease (oral, ocular, biological, extra glandular, life impact) via literature reviews and focus groups; and 2) Conduct a Delphi exercise of generated domains in SjD to gain consensus agreement and inform a core domain set; and 3) Generate a core domain set and seek approval from the OMERACT community. The research proposed is innovative because for the first time, it engages all stakeholders from at least three continents from the start of the process for generation and selection of instruments to measure response in SjD clinical trials.