

**Report for YODA Protocol 2019-4015**  
**6/22/2022**

**1. Objective**

We proposed a series of quantitative analyses using SIRROUND-D/SIRROUND-T data in support of the Center for Drug Evaluation and Research Clinical Outcome Assessment submission of PROMIS Fatigue in RA Drug Development Tool (DDT) qualification submission. Qualification would enable drug developers to issue labelling claims based on the patient reported outcome of fatigue and allow use of patient-reported fatigue as an endpoint measure in RA treatment trials. Using this data, we will examine and compare the psychometric characteristics, including score distribution and correlation, internal consistency, test-retest reliability, convergent and known groups validity, and responsiveness to change.

**2. Methods Used (please note whether your methods used were consistent with your original proposal, or whether you revised your methods during your analysis). If your analyses were not completed, please provide an explanation (i.e. PI could not allocate resources to this project or analyses were started but data did not contain needed variables). This information is helpful for the YODA Project to assess barriers to project completion.**

We did not conduct the proposed analyses. Though we entered the portal to inspect the data, we decided not to use the SIRROUND-D/SIRROUND-T for this project. Therefore, no formal analysis was conducted.

**3. Results (please use tables where applicable) (please provide preliminary findings even if full analyses were not completed)**

No analyses were completed, so no results are available.

**4. Conclusions (please note N/A if your analyses were not completed)**

N/A