Rheumatoid Arthritis Working Group

Presented at the Fourth Annual PRO Consortium Workshop – Silver Spring, MD – April 24 - 25, 2013

Background

Rationale for Rheumatoid Arthritis (RA) Working Group (WG)

- PRO Consortium member representatives and FDA advisors identified RA as a priority area with an unmet need for a 'fit-for-purpose' PRO measure, as defined by the FDA, for use in evaluating treatment benefit in RA clinical trials

Goal of the RA WG

- To develop and qualify a PRO instrument that assesses RA-related fatigue and support product labeling claims of treatment benefit.

In the Scoping Stage Summary Document submitted to the FDA in September 2011, the RA WG proposed that the most important unmet measurement needs in RA trials were standardized PRO instruments assessing RA-related symptoms and RA-defining decrements in physical function. The FDA, in its response in December 2011, acknowledged that "the PRO measures currently used in RA patients could be improved to meet current standards for measurement. We agree to participate in the qualification process for both PRO instruments you have proposed provided that instrument development includes involvement of representatives from the rheumatology community including OMERACT and ACR."

In May 2012, a few members of the RA WG met with RA patients and clinical experts to assess interest in a joint development activity. Experts and patients were eager to participate in an activity, which would include representatives from FDA, clinical societies, and other key stakeholders. Subsequently, PRO Consortium leadership, supported by the RA WG, organized a consensus development workshop to identify a path forward (see Updates).