CRITICAL PATH INSTITUTE

# C-Path Receives FDA Qualification for Rheumatoid Arthritis Fatigue Measure

*The PROMIS® Fatigue Short Form 10a, derived from the FACIT Fatigue Scale, becomes the sixth outcome assessment qualified through C-Path's Patient-Centered Evidence Consortium, with evidence supporting its use in tracking meaningful patient improvement over time.*

**TUCSON,** Ariz., August 18, 2026 — Critical Path Institute's® (C-Path) Patient-Centered Evidence Consortium today announced the qualification of the PROMIS® Fatigue Short Form 10a by the U.S. Food and Drug Administration (FDA).

The PROMIS Fatigue Short Form 10a, derived from the FACIT Fatigue Scale, assesses fatigue in adults with rheumatoid arthritis (RA). The consortium's RA Working Group worked pre-competitively to compile the evidence necessary to support this qualification effort. Qualification of the PROMIS Fatigue Short Form 10a marks a major milestone for the RA Working Group and is the consortium's first qualification supported by evidence demonstrating longitudinal measurement properties in addition to content validity and cross-sectional evidence. The evidence shows the measure can detect improvement and can support interpretation of clinically meaningful within-patient improvement in RA clinical trials.

Eli Lilly and Company Senior Director and co-chair of the RA Working Group April Naegeli, Ph.D., said, "The availability of longitudinal evidence translates to direct value for sponsors and regulators, because it means less evidence will need to be generated, submitted, and reviewed for future investigational new drug discussions involving this measure in clinical trials, saving everyone time and cost."

RA is the most common form of inflammatory arthritis and is associated with debilitating symptoms that fluctuate over time, significantly affecting patients' longevity and quality of life. In addition to symptoms such as pain, impaired physical function, stiffness, sleep disturbance, and emotional distress, patient and clinician input identified fatigue as a common, persistent, disabling, and high-priority symptom in RA. PROMIS Fatigue Short Form 10a was derived as a patient-reported measure of fatigue severity for the evaluation of fatigue-related clinical benefit in RA treatment trials.

The working group acknowledges the crucial contributions of its research partner, Northwestern University, throughout all aspects of this process. "This qualification effort began by listening to patients and understanding how fatigue affects their daily lives," said David Cella, Ph.D., professor emeritus of the Feinberg School of Medicine at Northwestern University. "Those insights highlighted the need for a fit-for-purpose measure of fatigue that accurately captures fatigue in people living with RA. Optimized through patient input and supported by the strong psychometric properties of the PROMIS Fatigue Item Bank, the PROMIS Fatigue Short Form 10a provides a rigorous yet efficient measure for evaluating fatigue in RA clinical trials."

"This qualification is an important step for people living with rheumatoid arthritis," said Healthy Motivation President and CEO Amye Leong, MBA. "By supporting the inclusion of fatigue as a meaningful outcome in clinical trials, it helps ensure that treatments are evaluated based on what matters most to patients and provides information that can support shared decision making between patients and their clinicians."

C-Path's Patient-Centered Evidence Consortium Executive Director Sonya Eremenco said, "This qualification demonstrates the power of sustained collaboration among patients, industry, academic researchers, and regulators. By bringing these perspectives together around rigorous measurement science, the consortium helps advance patient-centered tools that can improve the evaluation of new therapies."

The qualification of the PROMIS Fatigue Short Form 10a represents an important advancement in patient-reported outcome assessment for fatigue in drug development and reflects FDA's commitment to patient-focused drug development through qualification of COAs that capture valid, reliable, and meaningful data.

Further information regarding the qualification is available on the FDA's website, and further information regarding licensing is available via FACIT.org.

**About Critical Path Institute**
Critical Path Institute® (C-Path) is an independent, nonprofit organization established in 2005 as a public-private partnership in response to the FDA's Critical Path Initiative. C-Path's mission is to lead collaborations that advance better treatments for people worldwide. Globally recognized as a pioneer in accelerating drug development, C-Path has established numerous international consortia, programs and initiatives that currently include more than 1,600 scientists and representatives from government and regulatory agencies, academia, patient organizations, disease foundations and pharmaceutical and biotech companies. With dedicated team members located throughout the world, C-Path's global headquarters is in Tucson, Arizona; C-Path's Europe subsidiary is headquartered in Amsterdam, Netherlands. For more information, visit c-path.org.

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