

C-Path receives COA qualification from FDA for the *Symptoms of Major Depressive Disorder Scale (SMDDS)*

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Tucson, AZ – December 18, 2017 [Critical Path Institute](#)'s (C-Path) [Patient-Reported Outcome \(PRO\) Consortium](#) announces its first clinical outcome assessment (COA) qualification from the US Food and Drug Administration (FDA) for the *Symptoms of Major Depressive Disorder Scale (SMDDS)*. This qualification of the *SMDDS* for exploratory use represents a major milestone for the PRO Consortium and specifically for the Depression Working Group, and is the culmination of a multi-year collaboration between FDA's Center for Drug Evaluation and Research (CDER) and the PRO Consortium.

The *SMDDS* is a 16-item, patient-reported outcome (PRO) measure developed to capture the core symptoms of major depressive disorder (MDD) that matter most to patients. "While measures are often developed by clinicians and/or measurement experts with some input and consultation from patients, the *SMDDS* development was driven by the patient voice from the very beginning and throughout every iteration—with clinicians and measurement experts acting as consultants and providing input as needed," said Elizabeth (Nicki) Bush, MHS, Director of the Patient-Focused Outcomes Center of Expertise at Eli Lilly and Company and Industry Co-Director of the PRO Consortium. She added, "This patient-centered approach, along with the close collaboration with regulators, has resulted in a robust symptom measure suitable for use in drug development. More important, however, the *SMDDS* measures what people with major depressive disorder have described as important and impactful, incorporating words they used to describe their experiences—ultimately allowing for meaningful and interpretable data."

The *SMDDS* signifies the advancement of PRO measurement in drug development for depression as well as FDA's commitment to capture the patient's voice through qualification of COAs that are meaningful to patients, valid, reliable, and responsive to treatment. Stephen Joel Coons, PhD, the PRO Consortium's Executive Director, affirmed that "The qualification of the *SMDDS* is an incredibly important achievement for the PRO Consortium. It is the result of a tremendous amount of time and effort invested by C-Path, our industry partners, clinical and measurement consultants, FDA, and the patients who volunteered to help us with this worthwhile project. The *SMDDS* has the potential to change the current measurement paradigm for assessing treatment benefit in MDD clinical trials."

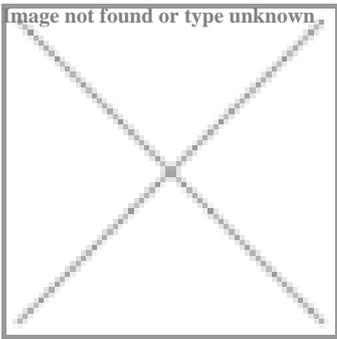
The qualification supports exploratory use of the *SMDDS* as a measure of symptoms of MDD in drug development. Drug developers are encouraged to discuss with FDA inclusion of this novel instrument in their MDD drug development programs. Further evaluation is needed on the instrument's longitudinal properties and the interpretation of clinically meaningful within-patient change in score. This information can be obtained in early-phase studies in drug development programs. As further supportive experience with

the *SMDDS* accumulates, the qualification could be expanded to include use of the *SMDDS* as part of a primary or secondary efficacy endpoint in confirmatory studies.

The Qualification Statement can be found at [FDA's Clinical Outcome Assessment Qualification Program Submissions Site \(https://tinyurl.com/yaocng6\)](https://tinyurl.com/yaocng6).

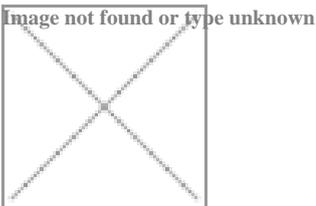
Further information about the *SMDDS* and how to access it is available by contacting proadmin@c-path.org.

About C-Path



Critical Path Institute (C-Path) is an independent, nonprofit organization established in 2005 with public and private philanthropic support from the Arizona community, Science Foundation Arizona, and the US Food and Drug Administration (FDA). C-Path's mission is to catalyze the development of new approaches that advance medical innovation and regulatory science, accelerating the path to a healthier world. An international leader in forming collaborations, C-Path has established numerous global, public-private partnerships that currently include over 1,450 scientists from government and regulatory agencies, academia, patient advocacy organizations, and dozens of pharmaceutical companies. C-Path is headquartered in Tucson, Arizona. For more information, visit www.c-path.org.

About the PRO Consortium



The PRO Consortium was formed in late 2008 in cooperation with the US Food and Drug Administration's (FDA) Center for Drug Evaluation and Research and the pharmaceutical industry, and formally launched in March 2009. The mission of the PRO Consortium is to establish and maintain a collaborative framework with appropriate stakeholders for the qualification of patient-reported outcome (PRO) instruments and other clinical outcome assessment (COA) tools that will be publicly available for use in clinical trials where COA-based endpoints are used to support product labeling claims.

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