CRITICAL PATH INSTITUTE

C-Path Awarded FDA Drug Development Tool Research Grant to Develop a Qualification Plan for the Symptoms of Major Depressive Disorder Momentary Assessment (SMDDMA)

C-Path's Patient-Reported Outcome (PRO) Consortium announced that it has been awarded a U.S. Food and Drug Administration (FDA) Drug Development Tool Research Grant in support of the qualification of the Symptoms of Major Depressive Disorder Momentary Assessment (SMDDMA) as a self-reported measure of symptom severity in individuals diagnosed with major depressive disorder (MDD). C-Path's PRO Consortium will carry out this work through its Depression Working Group 2.0. The SMDDMA is intended to facilitate the more timely assessment of the onset of symptom relief in persons with MDD.

The project has two aims. The first is to design a quantitative pilot study to generate evidence of the SMDDMA's cross-sectional measurement properties to support its qualification under FDA's Clinical Outcome Assessment Qualification Program. The second aim is to prepare a Qualification Plan for the SMDDMA for submission to FDA to advance the qualification of the measure.