C-Path Awarded FDA Drug Development Tool Research Grant to Develop a Qualification Plan for the PROMIS® Short Form v2.1—Physical Function-Multiple Sclerosis 15a (PROMIS PFMS—15a)

C-Path's Patient-Reported Outcome (PRO) Consortium announced today it has been awarded a U.S. Food and Drug Administration (FDA) Drug Development Tool Research Grant in support of the qualification of the PROMIS® Short Form v2.1—Physical Function-Multiple Sclerosis 15a (PROMIS PFMS—15a) as a self-reported measure of physical function in individuals diagnosed with all forms of multiple sclerosis (MS). C-Path's PRO Consortium will carry out this work through its Multiple Sclerosis Working Group. The PROMIS PFMS—15a is intended to be used as a secondary endpoint measure in clinical trials to better assess and understand the clinical benefit of new treatments on physical function in persons with MS.

The project has two aims. The first is to develop a cross-sectional and longitudinal statistical analysis plan to guide analyses of data generated by a United Kingdom MS Register study, in which 600 participants with MS are being recruited to complete the PROMIS PFMS—15a, in addition to other measures of interest, at multiple time points. The second aim is to prepare a Qualification Plan for the PROMIS PFMS—15a following the FDA Center for Drug Evaluation and Research's Clinical Outcome Assessment (COA) Qualification Plan content outline for submission to FDA to advance the qualification of the measure.