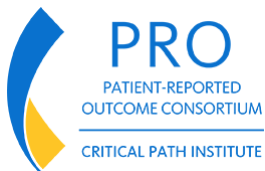

C-Path Receives Qualification from FDA for the Asthma Daytime Symptom Diary (ADSD) and the Asthma Nighttime Symptom Diary (ANSD)



TUCSON, Ariz., April 9, 2019 — Critical Path Institute’s (C-Path) Patient-Reported Outcome (PRO) Consortium announces U.S. Food and Drug Administration (FDA) qualification of two new clinical outcome assessment tools: *the Asthma Daytime Symptom Diary (ADSD)* and the *Asthma Nighttime Symptom Diary (ANSD)*. The qualification of the *ADSD* and the *ANSD* represents a major milestone for the PRO Consortium and specifically for the Asthma Working Group. It is the culmination of a multi-year collaboration between FDA’s Center for Drug Evaluation and Research (CDER) and the PRO Consortium.

The *ADSD* and the *ANSD* are each 6-item, PRO measures developed to document the core symptoms of asthma in adults and adolescents with a clinical diagnosis of mild to severe persistent asthma.

“Asthma symptoms have a substantial impact on patients, including limiting the ability to participate in daily activities and disrupting sleep. The qualification of the *ADSD* and the *ANSD* is a significant advance in our ability to document the patient’s experience of asthma symptoms in clinical trials,” stated Linda Nelsen, MHS, Senior Director and Head, Patient Centered Outcomes, Value Evidence and Outcomes, at GlaxoSmithKline and co-chair of the PRO Consortium’s Asthma Working Group.

“The development of the *ADSD* and *ANSD* represents a close collaboration of clinicians, measurement experts, and regulators focused on developing a robust measure of asthma symptoms,” Nelsen added. “Most importantly, the *ADSD* and *ANSD* were developed with extensive involvement of people living with asthma to clearly define the experience of asthma symptoms and the relative importance of those symptoms from their perspective. Thus, the *ADSD* and *ANSD* bring the patient’s voice into clinical trials in a way that allows the quantification of important concepts of patient experience in treatment.”

Sonya Eremenco, MA, Associate Director of the PRO Consortium, said, “Sponsors of asthma treatment trials have been using a variety of asthma symptom measures over the years, but we now have a standard set of symptom measures created via a multi-stakeholder, precompetitive collaboration that can be used in asthma drug development programs. This is a significant step toward providing enhanced consistency and comparability in the evaluation of the patient-focused clinical benefit from new asthma drugs.”

CDER has determined that the *ADSD* and *ANSD* have demonstrated adequate evidence of content validity and cross-sectional measurement properties (i.e., internal consistency reliability, test-retest reliability, convergent validity and known-groups validity) to measure symptoms of asthma in adolescents and adults.

Drug developers seeking to use the *ADSD* or *ANSD* as a primary or secondary endpoint measure in confirmatory studies should discuss plans with the appropriate CDER review division. It is recommended to use the *ANSD* with the *ADSD* to

better characterize the drug effect and understand the measurement properties of each instrument. Further evaluation is needed on the instruments' longitudinal properties and the interpretation of clinically meaningful within-patient change in score.

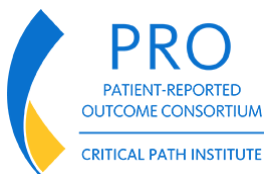
The Qualification Statement can be found on the FDA's Drug Development Tools [Qualified Clinical Outcome Assessments \(COA\)](#) web page.

Further information about the ADSD and the ANSD, and how to access these measures, is available by contacting proadmin@c-path.org.



About C-Path

C-Path (Critical Path Institute) is an independent, nonprofit organization established in 2005 as a public and private partnership. 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 consortia that currently include over 1,500 scientists from government and regulatory agencies, academia, patient organizations, disease foundations, and dozens of pharmaceutical and biotech companies. C-Path is headquartered in Tucson, Arizona, with additional staff in multiple remote locations. For more information, visit www.c-path.org.



About C-Path's Patient-Reported Outcome (PRO) Consortium

The Patient-Reported Outcome (PRO) Consortium was formed in 2008 by Critical Path Institute in cooperation with the US Food and Drug Administration's Center for Drug Evaluation and Research and the pharmaceutical industry. The mission of the PRO Consortium is to establish and maintain a collaborative framework with appropriate stakeholders for the qualification of PRO measures 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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