C-Path Receives COA Qualification from FDA for the *Non-Small Cell Lung Cancer Symptom Assessment Questionnaire (NSCLC-SAQ)*

TUCSON, Ariz. – May 7, 2018 — Critical Path Institute's (C-Path) Patient-Reported Outcome (PRO) Consortium announces its second clinical outcome assessment (COA) qualification from the US Food and Drug Administration (FDA). The qualification of the *Non-Small Cell Lung Cancer Symptom Assessment Questionnaire (NSCLC-SAQ)* for exploratory use represents another major milestone for the PRO Consortium and, specifically, for the NSCLC Working Group. This is the culmination of a multi-year collaboration between FDA's Center for Drug Evaluation and Research (CDER) and the PRO Consortium.

The *NSCLC-SAQ* is a 7-item, patient-reported outcome measure. As stated by Astra M. Liepa, PharmD, Research Advisor, Global Patient Outcomes and Real World Evidence, Eli Lilly and Company and co-chair of the PRO Consortium's NSCLC Working Group, "The *NSCLC-SAQ* was developed with involvement of key stakeholders, including clinical experts, FDA, measurement experts, clinical trial sponsors, and, most importantly, patients. The content of the *NSCLC-SAQ* was based on direct input from patients with NSCLC and assesses symptoms that these patients consider to be of greatest importance. The *NSCLC-SAQ* provides an opportunity for the patient's voice to be incorporated into drug development as a measure of patient-relevant symptom benefit."

The *NSCLC-SAQ* signifies an important advance in PRO measurement in patients with NSCLC. It is further evidence of FDA's commitment to patient-focused drug development through qualification of COAs that provide valid and reliable information that is meaningful to patients. Stephen Joel Coons, PhD, the PRO Consortium's Executive Director, stated that "The qualification of the *NSCLC-SAQ* is another important achievement for C-Path, the PRO Consortium, and the many collaborators involved. We are extremely grateful for the human and financial resources invested over multiple years by multiple stakeholders, including the patients who volunteered their time and insight to help us with this valuable initiative."

The qualification supports exploratory use of the *NSCLC-SAQ* as a measure of symptoms of NSCLC in drug development. Drug developers are encouraged to discuss with FDA inclusion of this novel instrument in their NSCLC 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 *NSCLC-SAQ* accumulates, the qualification could be expanded to include use of the *NSCLC-SAQ* as part of a secondary efficacy endpoint in confirmatory studies.

The Qualification Statement can be found at FDA's Clinical Outcome Assessment Qualification Program Submissions Site.

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

About the organizations:

Critical Path Institute (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.

Patient-Reported Outcome (PRO) Consortium

The Patient-Reported Outcome (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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