Qualification Statement

Qualification of Non-Small Cell Lung Cancer Symptom Assessment Questionnaire (NSCLC-SAQ): A Patient-Reported Outcome Instrument

Date: April 4, 2018

DDT Type: Clinical Outcome Assessment (COA)

DDT Tracking Number: DDTCOA-000009

Referenced COA: Non-Small Cell Lung Cancer Symptom Assessment Questionnaire (NSCLC-SAQ)

Type of COA: Patient-Reported Outcome (PRO) Instrument

The Center for Drug Evaluation and Research (CDER) has determined that the NSCLC-SAQ 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 non-small cell lung cancer (NSCLC) in the context of use described below. Sponsors should engage the review division early and throughout drug development to discuss the use of NSCLC-SAQ to support labeling claims for their drug development programs.

Section I: COA Concept of Interest

The NSCLC-SAQ total score measures overall severity of the following NSCLC symptoms: cough, pain, dyspnea, fatigue, and appetite.

Section II: Context of Use

This qualification statement supports the NSCLC-SAQ as a measure of overall symptom severity of NSCLC in drug development. Further evaluation is needed on the instrument's longitudinal measurement properties (e.g., ability to detect change) and the interpretation of clinically meaningful within-patient change in score. It is recommended that this information be obtained in early phase studies in drug development programs.

Sponsors seeking to use the NSCLC-SAQ in their drug development program should discuss early with the appropriate CDER review division.

A. Study population

The recommended target patient population is described as follows:

- Adults aged 18 years and older
- Diagnosis of Stage IIIB or IV NSCLC
- Treatment naïve (i.e., no prior chemotherapy for Stage IIIB or IV NSCLC or not having received adjuvant chemotherapy for NSCLC within 6 months of study enrollment)
- Treated (i.e., received chemotherapy within 6 months and recovered from any prior treatment related toxicities/adverse events to CTCAE v4.03 grade 1 or better)

B. Labeling or promotional claim(s) based on the COA

After the NSCLC-SAQ's longitudinal measurement properties and the interpretation of clinically meaningful within-patient change have been established within the context of use, the NSCLC-SAQ total score is intended to support labeling claims related to change in overall symptoms of NSCLC.

Section III: Interpretation of Change

Information to support threshold(s) for clinically meaningful within-patient change(s) in the NSCLC-SAQ total score is needed. Data to interpret the clinically meaningful within-patient change in the NSCLC-SAQ total score should be gathered and evaluated in early phase development to establish the clinically meaningful within-patient change prior to use of the NSCLC-SAQ in studies intended to support labeling claims with this instrument.

Section IV: Contact Information for Access to the Qualified COA

Patient-Reported Outcome Consortium
Critical Path Institute
1730 E. River Road
Tucson, AZ 85718

For more information, please send email to: procadmin@c-path.org; Subject: NSCLC-SAQ Inquiry

Instructions for Use in a Regulatory Submission: Please reference DDT COA #000009 in your regulatory application.