# Clinical Outcome Assessments (COA) Qualification Program
# DDT COA #000133: Small Cell Lung Cancer (SCLC) Symptom Measure
# Letter of Intent

## Administrative Structure:

***Description of the submitter including, but not limited to, principal investigator(s), working group member(s), institutions, and contact information not contained within the cover letter.***

This proposal is being submitted by the Patient-Reported Outcome (PRO) Consortium at the Critical Path Institute (C-Path).

The PRO Consortium enables pre-competitive collaboration that leverages human and financial resources from multiple stakeholders. The PRO Consortium's Small Cell Lung Cancer (SCLC) Working Group currently has members representing the following pharmaceutical firms: AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Genentech/Roche, GSK, J&J/Janssen, Lilly, Merck, and Novartis. C-Path's principal investigator is Stephen Joel Coons, PhD, Executive Director of the PRO Consortium.

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## Concept(s) of Interest (COI) for Meaningful Treatment Benefit:

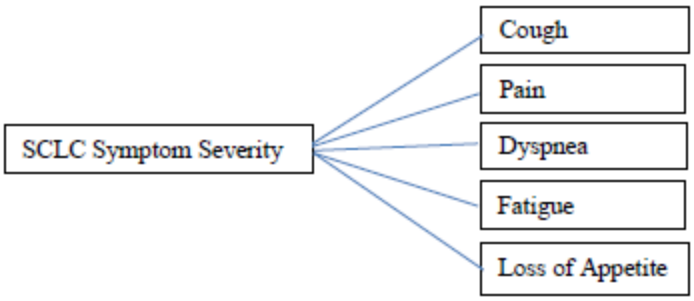
***A description of the meaningful aspect of patient experience that will represent the intended benefit of treatment (e.g., presence/severity of symptoms, limitations in performance of daily activities).***

The concept of interest is the self-reported severity of small cell lung cancer (SCLC) symptoms in adults. As currently hypothesized, the core symptoms are as follows: cough, pain, dyspnea, fatigue, and loss of appetite.

***Provide a conceptual framework for the COA(s)***

Figure 1 provides the hypothesized conceptual framework for the proposed SCLC symptom measure.

**Figure 1. Hypothesized Conceptual Framework for the proposed SCLC symptom measure**




## Context of Use for COA Qualification:

***Targeted study population including a definition of the disease and selection criteria for clinical trials (e.g., baseline symptom severity, patient demographics, comorbidities, language/culture groups).***

The proposed SCLC symptom measure is intended to assess changes in symptom severity for adults who have been diagnosed with SCLC.

The target population is comprised of adults (ages 18 and older) with a clinician-confirmed diagnosis of limited or extensive stage SCLC with Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2, regardless of line of therapy being administered.

***Targeted study design and statistical analysis plan (includes the role of the planned COA in future drug development clinical trials, including the planned set of primary and secondary endpoints with hierarchy, if appropriate*).**

The score resulting from the proposed SCLC symptom measure will be positioned to derive a secondary endpoint in SCLC treatment trials. It is likely that the primary endpoint(s) in these trials would be progression-free survival, overall survival, or objective response rate.

The specific endpoint selection, positioning, and measurement approach will be determined by the study sponsor in concert with the appropriate regulatory review agencies.

A statistical analysis plan for an SCLC treatment trial cannot be developed in the absence of a specific study protocol, which does not exist at this time.

***Applicable study settings for future clinical trials***

- ***Geographic location with language/culture groups***
  The proposed SCLC symptom measure will be translated as needed and is intended for use in multinational trials or trials within a single country where multiple language and cultural groups may be enrolled.

- ***Other study setting specifics (e.g., inpatient versus outpatient)***
  The target population is adult (ages 18 and older) outpatients who have been diagnosed with SCLC, regardless of type or line of treatment.

## <u>COA Type:</u> Patient- Reported Outcome (PRO)