DRUG DEVELOPMENT TOOL
LETTER OF INTENT DETERMINATION
DDT COA #000133

Stephen Joel Coons, PhD
Executive Director, PRO Consortium
Critical Path Institute
1730 E. River Road
Tucson, AZ 85718

Dear Dr Coons:

We have completed our review of the Letter of Intent (LOI) for Drug Development Tool (DDT) COA #000133 received on March 25, 2020, by the CDER Clinical Outcome Assessments (COA) Qualification Program, submitted under section 507 of the Federal Food, Drug, and Cosmetic Act.

The LOI is for the small cell lung cancer (SCLC) symptom measure, a patient-reported outcome, proposed for the assessment of SCLC symptom severity in adult patients (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.

FDA has completed its review and has agreed to accept your LOI into the CDER COA Qualification Program.

FDA's response to the questions included in the LOI can be found below.

1. **Does the Agency agree with the proposal to evaluate the *NSCLC-SAQ* for use in SCLC patients?**

   FDA's response: Yes, we agree.

2. **Does the Agency agree that conducting qualitative interviews among SCLC patients is an appropriate next step, using a modified version of the *NSCLC-SAQ*, to achieve concept confirmation and ensure the appropriateness of the content of the measure in this patient population?**

   FDA's response: Yes, we agree that conducting qualitative interviews is an appropriate next step; however, the original version of the NSCLC-SAQ should be used and modifications made based on the data obtained from your qualitative and quantitative studies.

3. **Does the Agency recommend the qualitative interview sample population include any particular patient subgroup, including genomic subtypes of SCLC?**

   FDA's response: There are currently no therapies targeting genomic tumor aberrations for SCLC. Therefore, we do not recommend including specific genomic subtypes of SCLC in your qualitative interview sample population. However, we recommend that your study population includes a reasonable proportion of subjects that are older given the higher prevalence of SCLC in the older population.

4. **Does the Agency agree with the proposed context of use?**

   FDA's response: Generally, adults with limited or extensive stage of SCLC with ECOG performance status of 0 to 2 is a reasonable target population. However, we have the following recommendations regarding your proposed study population:

   - Consider assessment of the instrument separately between limited and extensive stage SCLC patients, given that baseline symptoms and treatment-related side effects can differ significantly between these two groups.

   - Furthermore, for the extensive stage SCLC population, we recommend that you consider assessing the instrument separately for patients receiving first-line treatment versus later lines of therapy. This is based on the differences that exist at baseline for these patients and the variability in treatment (i.e., upfront combination therapy versus single agent commonly used in later lines).

The next milestone submission you would be working towards is a Qualification Plan (QP). You may submit your qualitative protocol and results for FDA review and comment prior to submitting your QP.

The following weblink contains the contents to include in your QP submission: www.fda.gov/media/123245/download. Please contact the CDER COA Qualification Program at COADDTQualification@fda.hhs.gov should you have any questions (refer to DDT COA #000133).

Sincerely,

Elektra J. Papadopoulos -S

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