



**DDT COA #000006**

**QUALIFICATION DETERMINATION**

Stephen Joel Coons, PhD  
Executive Director, PRO Consortium  
Critical Path Institute  
1730 E. River Road  
Tucson, AZ 85718  
Email: [SJCoons@c-path.org](mailto:SJCoons@c-path.org)

Dear Dr. Coons:

On behalf of the qualification review team, in reference to your qualification review package submitted May 18, 2018 for the Asthma Daytime Symptom Diary (ADSD) and the Asthma Nighttime Symptom Diary (ANSD), we have qualified the ADSD and the ANSD as measures of asthma symptoms for use in the context described in the qualification statement. Attached you will find the qualification statement for the ADSD and the ANSD, which describes the instruments and their qualified context of use.

These instruments have demonstrated adequate evidence of content validity and cross-sectional measurement properties. As additional longitudinal data become available, we encourage you to submit this information for review. This review may lead to a revised qualification statement(s) reflecting the complete measurement properties of the ADSD and ANSD. We also ask you to discuss with the Agency how to submit this information when the time is appropriate.

Please note that, at this time, 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 supportive evidence is required to characterize whether these two instruments (ADSD and ANSD) provide different information related to asthma symptoms.

Please contact the COA Staff at [COADDTQualification@fda.hhs.gov](mailto:COADDTQualification@fda.hhs.gov) should you have any questions (refer to DDT COA #000006).

Sincerely,

Elektra Papadopoulos, MD, MPH  
Associate Director  
Clinical Outcome Assessments Staff  
Office of New Drugs  
Center for Drug Evaluation and Research

Banu Karimi-Shah, MD  
Deputy Director (Acting)  
Division of Pulmonary, Allergy and Rheumatology  
Products (DPARP)  
Office of New Drugs  
Center for Drug Evaluation and Research