

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

Email: SJCoons@c-path.org

April 4, 2018

Dear Dr. Coons,

On behalf on the qualification review team, in reference to your qualification review package submitted March 30, 2017 for Non-Small Cell Lung Cancer Symptom Assessment Questionnaire (NSCLC-SAQ), we have qualified the NSCLC-SAQ for exploratory use. Attached you will find the qualification statement for the NSCLC-SAQ, which describes the NSCLC-SAQ and its qualified context of use.

If you have any questions, please contact the COA Staff via email at coaddtqualification@fda.hhs.gov. Please reference DDT #000009.

Sincerely,

Elektra J.

Digitally signed by Elektra J. Papadopoulos -S DN: c=US, c=U.S. Government, ou=HHS, ou=Poople.

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Elektra Papadopoulos, MD, MPH Associate Director Clinical Outcome Assessments Staff Office of New Drugs Center for Drug Evaluation and Research Patricia Digitally signed by Patricia Keegan -S DN: cuLS, cuLS, Government, ou-HTS, ou-Fople, un-People, un-Pe

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