DRUG DEVELOPMENT TOOL
QUALIFICATION PLAN DETERMINATION
DDT COA #000079

David Cella, PhD
Professor and Chairman
Department of Medical Social Sciences
Northwestern University
633 N. St. Clair, Suite 1900
Chicago IL 60611

Dear Dr Cella:

We have completed our review of the Qualification Plan (QP) for Drug Development Tool (DDT) clinical outcome assessment (COA) #000079 received on July 30, 2019 and the amended QP received on January 22, 2020 by the CDER COA DDT Qualification Program, submitted under section 507 of the Federal Food, Drug, and Cosmetic Act.

The QP is for the PROMIS Short Form v2.0 – Physical Function 8c, a patient-reported outcome (PRO) instrument, proposed for the assessment of physical function in adult patients with advanced solid tumors or hematologic malignancies of any primary site or origin (i.e., Stage III-IV) receiving active anti-cancer therapy.

FDA has completed its review and has agreed to accept your QP. FDA's response to the questions included in the QP can be found below.

Question 1: Does the agency agree that the qualification plan, including the plan for future analyses, is acceptable?

FDA Response: We agree that the proposed qualification plan (including the plan for future analyses), in principle, appears reasonable.

Question 2: Does the agency agree that submission of the final qualification package for limited context of use can proceed?

FDA Response: Please see FDA Response to Question 1.

The Full Qualification Package (FQP) for limited context of use can proceed. However, the FQP should address the scientific issue(s) outlined below:

- Evidence (including rationale) supporting that the test-retest reliability data on the 3 of 8 items (PFA9, PFA21, PFA1) featured in the PROMIS Short Form v2.0 – Physical Function 8c from the unpublished dataset complied by Dr. Yost is

generalizable to the full 8 items in the PROMIS Short Form v2.0 – Physical Function 8c.

- Evidence (including rationale) supporting that the known-groups validity data on the 5 of 8 items featured in the PROMIS Short Form v2.0 – Physical Function 8c from the MY Health dataset is generalizable to the full 8 items in the PROMIS Short Form v2.0 – Physical Function 8c.

Please contact the CDER COA Qualification Program at COADDTQualification@fda.hhs.gov should you have any questions (refer to DDT COA #000079).

Sincerely,

Elektra J. Papadopoulos -S

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Elektra Papadopoulos, MD, MPH
Director (acting)
Division of Clinical Outcome Assessment
Office of New Drugs
Center for Drug Evaluation and Research

Paul G. Kluetz -S

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Paul Kluetz, MD
Deputy Director
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