DRUG DEVELOPMENT TOOL
LETTER OF INTENT DETERMINATION
DDT COA #000095

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Temple University - College of Public Health
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Christopher B Forrest MD, PhD
Children's Hospital of Philadelphia
Roberts Center for Pediatric Research
Applied Clinical Research Center, 11th Floor, 11464
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Philadelphia, PA 19146

Dear Drs Tucker and Forrest:

We have completed our review of the Letter of Intent (LOI) for Drug Development Tool (DDT) COA #000095 received on August 22, 2019 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 PROMIS® Pediatric Chronic Kidney Disease Short Form – Fatigue (PROMIS® Pediatric CKD – Fatigue), a Patient-reported outcome (PRO), proposed for the assessment of fatigue associated with CKD in children between 8-17 years of age with CKD.

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

In preparing to submit a Qualification Plan (QP), please ensure that the QP submission addresses the scientific issues and the recommendations outlined below.

a. We recommend that you consider including alternative items to help characterize fatigue in the target population of CKD patients. Consider the potential inclusion of alternative items from the item bank, to reflect what patients experience in their everyday lives.
b. Consider including other items that may help reflect additional aspects of fatigue that are relevant to CKD patients (e.g., whether a patient needs to take naps during the day or whether patients have needed to miss more school days when they experience more severe fatigue).

2. You may consider expanding your proposed context of use to patients with more severe CKD (i.e., those who are on dialysis). From a clinical perspective, fatigue in these patients is likely to be more severe and will be important to capture the degree of fatigue and improvement for this subtype of CKD patients.

Please contact the CDER COA Qualification Program at COADDTQualification@fda.hhs.gov should you have any questions (refer to DDT COA #000095).

Sincerely,

Elektra J. Papadopoulos -S

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