DRUG DEVELOPMENT TOOL
LETTER OF INTENT DETERMINATION
DDT COA #000119

Carole A Tucker PhD
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, Rm 11464
2716 South Street
Philadelphia, PA 19146-2305

Dear Drs Tucker and Forrest:

We have completed our review of the Letter of Intent (LOI) for Drug Development Tool (DDT) COA #000119 received on September 16, 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 the PROMIS® Pediatric Chronic Kidney Disease Short Form- Sleep Disturbance, a patient-reported outcome (PRO), proposed for the assessment of sleep disturbance related to chronic kidney disease in children between 8-17 years of age with stages 2-4 CKD.

We have agreed to accept your LOI into the CDER COA Qualification Program. Below are comments related to the PROMIS® Pediatric Chronic Kidney Disease Short Form- Sleep Disturbance that we recommend you consider in your future submission of the Qualification Plan (QP) for the DDT (see link to QP outline below).

Comment 1: The targeted population you had indicated is children ages 8-17 years. Please provide evidence that patients as young as eight years can validly and reliably self-report on their symptoms associated with sleep disturbance.

- We have concerns with the proposed 7-day recall period as some children may not be able to recall accurately over a seven-day period. Please provide evidence and rationale for selecting a 7-day recall period.

Comment 2: As part of a future submission, provide rationale based on qualitative and quantitative research for choosing to move forward with the current short form rather than exploring inclusion of additional or alternative items from the PROMIS® Sleep Disturbance item bank. It is possible that other items in the item bank might be more appropriate for assessing sleep disturbance concepts in pediatric CKD patients.

In preparing to submit a QP, please ensure that the QP submission addresses the scientific issues and the recommendations included in the QP outline (https://www.fda.gov/drugs/drug-development-tool-qualification-programs/clinical-outcome-assessments-qualification-program-resources-stage).

Please contact the CDER COA Qualification Program at COADDTQualification@fda.hhs.gov should you have any questions (refer to DDT COA #000119).

Sincerely,

Elektra J. Papadopoulos -S

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