DRUG DEVELOPMENT TOOL
QUALIFICATION DETERMINATION
DDT COA #000005

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

Dear Dr Coons,

We have completed our review of the Full Qualification Package (FQP) for Drug Development Tool (DDT) COA #000005 received on December 21, 2018, by the CDER Clinical Outcome Assessments (COA) Qualification Program, submitted under section 507 of the Federal Food, Drug, and Cosmetic Act.

FDA has completed the review of your FQP for the Diary for Irritable Bowel Syndrome Symptoms–Constipation (DIBSS-C) and is qualifying the measures of abdominal pain, abdominal symptoms (abdominal pain, discomfort, bloating), complete spontaneous bowel movement frequency (stool frequency, incomplete bowel movements) and straining with bowel movements based on the DIBSS-C for the context of use described in the attached qualification statement.

Full details regarding qualification determinations can be found on our Qualified COAs website,[1] which is updated regularly. Please contact DCOA at COADDTQualification@fda.hhs.gov should you have any questions (refer to DDT COA #000005).

Sincerely,

Elektra J. Papadopoulos -S
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Elektra Papadopoulos, MD, MPH
Director (Acting)
Division of Clinical Outcome Assessment
Office of Drug Evaluation Science
Office of New Drugs
Center for Drug Evaluation and Research

Juli A. Tomaino -S
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Juli Tomaino, MD
Deputy Director
Division of Gastroenterology
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

[1] https://www.fda.gov/drugs/development-approval-process-drugs/qualified-clinical-outcome-assessments-coa