



**DRUG DEVELOPMENT TOOL
DDT COA #000148**

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

Dear Dr Coons:

We are writing in reference to the Drug Development Tool (DDT) Clinical Outcome Assessment (COA) #000005 (DDT COA #000005) within the CDER COA Qualification Program. DDT COA #000005 was originally assigned to the development of three patient-reported outcome (PRO) measures: one for Irritable Bowel Syndrome- Constipation (IBS-C), one for IBS- Diarrhea (IBS-D), and one for IBS-Mixed (IBS-M).

This letter officially assigns DDT COA #000148 to the development of a PRO measure for IBS-D. Please contact the CDER COA Qualification Program at COADDTQualification@fda.hhs.gov should you have any questions.

Sincerely,

Kimberly Chiu, PharmD
Regulatory Project Manager
Clinical Outcome Assessments Staff
Office of New Drugs
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