

**DRUG DEVELOPMENT TOOL  
21CC Transition  
DDT COA #000004**

Stephen Joel Coons, Ph.D.  
Executive Director, PRO Consortium  
Critical Path Institute  
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Tucson, AZ 85718

Dear Dr Coons:

Thank you again for agreeing to continue your ongoing clinical outcome assessment (COA) development effort under the process articulated in section 507 of the Federal Food, Drug, and Cosmetic Act as added by the 21st Century Cures Act (section 507 process). The section 507 process includes three submission types; 1) a Letter of Intent (LOI), 2) a Qualification Plan (QP), and 3) a Full Qualification Package (FQP).

As part of this transition to the section 507 process, the next step for your project, DDT COA #000004 (a tool to assess day-to-day functioning in adult patients with mild cognitive impairment due to Alzheimer's disease using a performance- based outcome assessment), would be the development of a QP. The QP is a submission that was not part of the legacy process. You may view the COA Qualification Plan outline at: [www.fda.gov/media/123245/download](http://www.fda.gov/media/123245/download).

Under the new process, all three stages are mandatory and all projects undergoing qualification must progress through the stages sequentially.

Please contact the CDER COA Qualification Program at [COADDTQualification@fda.hhs.gov](mailto:COADDTQualification@fda.hhs.gov) should you have any questions (refer to DDT COA #000004).

Sincerely,

Kimberly Chiu, PharmD  
Regulatory Project Manager  
Clinical Outcome Assessments Staff  
Office of New Drugs  
Center for Drug Evaluation and Research