pDDT COA #2019-01 **LOI Determination Letter**

Professor Stanton Newman
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Dear Professor Stanton Newman,

We have completed our review of the letter of intent (LOI) submission for pDDT COA #2019-01 received on December 6, 2018, by CDER's Clinical Outcomes Assessment (COA) Qualification Program.

The submission included an LOI for PostopQRS, a PRO, PerfO and ClinRO, proposed to comprehensively assess the recovery process of patients undergoing all forms of surgery and anesthesia.

Following careful consideration of your submission, we have concluded that we are unable to accept this instrument into the COA Qualification Program as there is not sufficient unmet need for this tool for drug development and regulatory decision-making. The PostopQRS attempts to incorporate and combine multiple COA instruments into a single overall score, which is not sufficiently well-defined for regulatory use. Additionally, there are existing assessment instruments currently available to capture the individual domains of the PostopQRS, e.g., pain scales, anesthesia satisfaction surveys, etc.

We regret that we cannot undertake further review under the qualification process. Should you wish to discuss this further or require any clarification, please contact the COA Staff at COADDTQualification@fda.hhs.gov. Please refer to pDDT COA #2019-01.

Sincerely,

Elektra J. Papadopoulos -S

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