DRUG DEVELOPMENT TOOL
LETTER OF INTENT DETERMINATION
DDT COA #000142

Dinesh Puppala, MS
Verily Life Sciences
269 E Grand Ave
San Francisco, CA 94080

Dear Mr. Puppala,

We have completed our review of the Letter of Intent (LOI) for Drug Development Tool (DDT) COA #000142 received on January 25, 2021 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 Virtual Motor Exam for Parkinson's disease, Part III Estimator (VME Part III), as measured by the Verily Study Watch, a Digital Health Technology (DHT) – Passive Monitoring COA, proposed for the assessment of motor symptom severity in adults who have been diagnosed with Parkinson's disease across the full range of disease progression.

We have completed our review and decided not to accept your LOI. We have the following comments:

The Verily Study Watch/VME III measures a change in digitally assessed parameters of a subset of Parkinson's disease motor signs from the MDS-UPDRS Part III (motor examination). However, the MDS-UPDRS Part III and the VME III are limited in their capacity to evaluate meaningful aspects of concepts of interest that are relevant to the patients' ability to function in day-to-day life. For example, a change in rigidity or finger tapping in the MDS-UPDRS Part III cannot be directly interpreted as being meaningful to patients. However, a change in speech, eating and dressing (as assessed in the MDS-UPDRS Part II) represents meaningful change in how patients function in daily life. Additionally, the Verily Study Watch/VME III is a remote assessment that provides an algorithmic representation of change in selected items of the MDS-UPDRS Part III. This raises additional concerns about the ability to interpret changes on the VME III measured by the Verily Study Watch as representing meaningful change in patients' ability to function. For example, it is unclear how the change in the digital signature for finger tapping (as measured by the Verily Study Watch) could be interpreted as representing meaningful change in patient function.

For these reasons, when evaluating drug efficacy in Parkinson's disease, the FDA prefers content that is more representative of daily life functioning (e.g., consistent with the MDS-UPDRS Part II or other similar instruments).

Please contact the CDER COA Qualification Program at COADDTQualification@fda.hhs.gov should you have any questions (refer to DDT COA #000142).

Sincerely,

Elektra J. Papadopoulos -S

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Elektra Papadopoulos, MD, MPH
Deputy Director (Acting)
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Center for Drug Evaluation and Research

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