DRUG DEVELOPMENT TOOL
LETTER OF INTENT DETERMINATION
DDT COA #000129

Kathryn Nolan
Corporate Development and Systems Analyst
MC10, Inc.
10 Maguire Rd, Bld 3, 1st Fl.
Lexington, MA 02421

Dear Ms. Nolan:

We have completed our review of the Letter of Intent (LOI) for Drug Development Tool (DDT) Clinical Outcome Assessment (COA) #000129 received on February 10, 2020**,** by the CDER COA Qualification Program, submitted under section 507 of the Federal Food, Drug, and Cosmetic Act.

The LOI is for the Advanced Gait Analysis (MC10 BioStamp nPoint®), a digital health technology (DHT), proposed for the assessment of progressive gait abnormality of ambulatory adults with pathogenic genetic mutation and CAG expansion indicative of Huntington's Disease (HD) with or without motor manifestations in home and professional healthcare settings during clinical trials or natural history studies.

FDA has completed review of your LOI and has determined that we are unable to accept your LOI into the CDER COA Qualification Program at this time. We have the following comments regarding your proposed gait assessment in the context of a clinical outcome assessment:

- A COA, by definition, measures or reflects how an individual feels, functions or survives. However, your proposed assessment tool does not appear to evaluate functioning in patients' daily life (e.g., ambulation), but rather subtle changes in certain gait parameters that might not impact functioning. Therefore, the meaningfulness to patients with regard to changes in gait parameters assessed using this instrument is unclear.

Therefore, at this time, the proposed gait assessment measured by MC10 BioStamp nPoint® appears to have limited utility as a COA for regulatory decision-making. You may wish to refer to the BEST glossary (https://www.ncbi.nlm.nih.gov/books/NBK338448) for definitions and examples of each type of medical product development tool to help you determine the most appropriate context of use for your proposed assessment.

Please contact the CDER COA Qualification Program at COADDTQualification@fda.hhs.gov should you have any questions (refer to DDT COA #000129).

Sincerely,

Elektra J. Papadopoulos -S

Digitally signed by Elektra J. Papadopoulos -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300170743, cn=Elektra J. Papadopoulos -S
Date: 2020.06.04 13:52:45 -04'00'

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

Eric P. Bastings -S

Digitally signed by Eric P. Bastings -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300158815, cn=Eric P. Bastings -S
Date: 2020.06.05 08:47:51 -04'00'

Eric Bastings, MD
Director (Acting)
Division of Neurology I
Office of Neuroscience
Office of New Drugs
Center for Drug Evaluation and Research