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To: jim.wang@sparktx.com
Cc: Morris, Nevitt
Subject: BLA 125610 Clinical Information Request 8.22.17
Date: Tuesday, August 22, 2017 11:28:22 AM
Attachments: image001.png

(File Attachment comment)
Hi Jim:

We are submitting the following Information Request from our clinical team regarding BLA 125610. Please respond accordingly.

Clinical Information Request:

We will use the term "MLMT score change" instead of "MLMT change score" (Applicant's term) to describe the difference between the MLMT score at baseline and the MLMT score at a follow-up visit in both our Advisory Committee (AC) meeting briefing document and presentation slides for BLA 125610. We feel that the term "MLMT score change" is easier for the AC members and audience to understand. We hope that the Applicant will adopt the term and modify their document and presentation slides accordingly.

Thanks,

Nevitt

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