

Davidson, Mark

From: Davidson, Mark
Sent: Tuesday, May 09, 2017 3:25 PM
To: 'Rizwana Sproule'
Cc: 'Alex Babayan'; 'Nadia Agopyan'
Subject: BLA 125643 Clinical Data Information Request 5.9.17

Importance: High

Follow Up Flag: Follow up
Due By: Wednesday, May 10, 2017 10:00 AM
Flag Status: Flagged

Hi Dr. Sproule,

Reference is made to the current BIOTR.xpt file for ZUMA1. There is no column for "Aperiod", and tumor measurements include those performed after retreatment. As with the ADTR.xpt file that required revision, we also note that the "MINSPDFL" flag includes flags for tumor measurements performed after retreatment. For efficacy analysis, submit a revised BIOTR.xpt file that

- a) adds the "Aperiod" column, and
- b) corrects the "MINSPDFL" flag to reflect the first KTE-C19 dose, in accordance with the main analysis plan.

Please respond by noon Friday May 12, 2017

Thank You

Mark L. Davidson, RHIA
Regulatory Project Manager
OTAT/CBER/FDA
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Phone: 240-402-8277
Fax:301-595-1303
mark.davidson@fda.hhs.gov

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