

Davidson, Mark

From: Davidson, Mark
Sent: Thursday, June 08, 2017 3:32 PM
To: 'Rizwana Sproule'
Cc: 'Nadia Agopyan'; 'Alex Babayan'
Subject: KITE Pharma 125643 Clinical IR 6.8.17

Importance: High

Dear Dr. Sproule,

We have the following request for additional information regarding the ZUMA1 datasets:

- 1) **Due 12 pm EST, Friday 6/9/2017:** ZUMA1 datasets: Reference is made to the 6/2/2017 information request regarding the incorrect response categorization for subject 101-006-002, and your response which stated that updated versions of ADEFF, ADTR, ADTTE, and BIOTR .xpt files would be provided. An updated ADTR.xpt file was not however submitted. For efficacy review, submit an updated ADTR.xpt file, incorporating corrections for subject 101-006-002 such that the maximal reduction in tumor burden reflects pretransplantation measurements.
- 2) For the ZUMA1 datasets with a 4/2017 cutoff date, submit SDTM files in addition to ADAM files to enable verification of data. Submit the SDTM files on the same date as the ADAM files (**by 6/23/2017** for investigator assessments, and **by 6/30/2017** for IRC). Include the SAS programs used to generate the ADAM files.

Thank You

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