

Davidson, Mark

From: Davidson, Mark
Sent: Monday, July 03, 2017 1:26 PM
To: 'Rizwana Sproule'
Cc: 'Nadia Agopyan'; 'Alex Babayan'
Subject: Kite Pharma BLA 125643 Clinical Information request June 3, 2017

Importance: High

Hello Dr. Sproule,

We have the following questions regarding ZUMA-1 datasets:

In the 6/26/2017 submission containing an overview of the updated ZUMA-1 efficacy outcomes per investigator, changes in some patients' response designation were described. In the new ZUMA1 datasets with a 4/2017 cut-off, the response rates per IRC also differs as compared to the datasets having a 1/2017 cut off. For efficacy review,

- Provide a list of all changes in overall response designation, both by IRC and by investigator, in the 4/2017 datasets as compared to earlier submissions.
- Apart from updates in outcome, provide a list of any other corrections made (for example, in patient or disease characteristics).

Submit this response by 12 pm EST, Thursday July 6, 2017.

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