

## Davidson, Mark

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**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.**

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](mailto:mark.davidson@fda.hhs.gov)

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