

Davidson, Mark

From: Davidson, Mark
Sent: Wednesday, May 24, 2017 11:09 AM
To: Rizwana Sproule (RSproule@KitePharma.com)
Cc: Nadia Agopyan (NAgopyan@KitePharma.com); 'Alex Babayan'
Subject: Kite Pharma BLA 125643 Clinical Information Request May 24, 2017

Importance: High

Dear Dr. Sproule,

We have the following IR regarding Kite BLA 125643 :

1. In the Analysis data reviewer's guide for ISS ZUMA-1 you explain the variables AENUM, CRSNUM and CRSAENUM, however can you further clarify it (i.e., what the numbers under each variable mean)
2. Please clarify which neurological or psychiatric symptoms triggered neuro flagging.
3. Neurologic symptoms occurring in the context of CRS may occur coincident with other symptoms of CRS or may arise when the other symptoms of CRS are resolving (Lee DW et al, Blood. 2014 Jul 10; 124(2): 188–195). It appears that delayed neuro and psych events were not included as part of your CRS. In order to capture all neuro and psych events that might occur in the context of CRS (concurrent or delayed events), please provide dataset for the following:
 - a. All neuro and psych events that occurred within 30 days from investigational product infusion
 - b. All neuro and psych events that occurred within 30 days of CRS.
 - c. All CRS events that occurred within 30 days of investigational product infusion:
 - i. Start and end date and study day of CRS (including onset and resolution of all grades) (Please indicate if CRS resolved and reoccurred for any time period)
 - ii. Start and end date and study day of highest CRS grade.
 - d. Please flag subjects who were retreated if events occurred during period 2
4. Please include subjects IDs for all events.

Please verify when received.

Please respond by COB EST, Thursday, May 25, 2017.

Thank You

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