

Davidson, Mark

From: Davidson, Mark
Sent: Tuesday, May 23, 2017 11:16 AM
To: Rizwana Sproule (RSroule@KitePharma.com)
Cc: Nadia Agopyan (NAgopyan@KitePharma.com); 'Alex Babayan'
Subject: Kite Pharma BLA 125643 Statistical Information Request May 23, 2017

Importance: High

Dear Dr. Sproule,

You used OVTPRSP2 in dataset RS.xpt as the central review disease response and used it in the efficacy analyses.

- a. Please clarify how this variable differs from others such as OVTPRSP1 or OVRNIN4 in rs.xpt which are also overall disease response assessments and why those are not used as central review disease response.
- b. Please explain how OVTPRSP2 was derived based on the two radiologists' readings and the oncologist assessment.
- c. What does "time point response" mean? Please clarify for variable RSTEST in rs.xpt why some of the test names have "time point response" in it but others do not.

Please respond by May 24, 2017.

Thank You

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