

Davidson, Mark

From: Davidson, Mark
Sent: Monday, May 22, 2017 12:48 PM
To: Rizwana Sproule (RSproule@KitePharma.com)
Cc: 'Alex Babayan'; Nadia Agopyan (NAgopyan@KitePharma.com)
Subject: Kite Pharma BLA 125643 Clinical Information Request May 22, 2017

Importance: High

Dear Dr. Sproule,

Reference is made to the most recent revision of the BIOTR.xpt dataset (ZUMA1 IRC tumor measurements), submitted 5/12/2017 in response to a 5/9/2017 information request. Per your response, to identify the minimum post-treatment SPD and associated % change from baseline for the mITT population for Period 1 only, one selects MITTFL=Y and APERIOD=1 and MINSPDFL=Y. However, of the 96/101 patients who had IRC response assessments, this strategy identifies only 93. The three missing patients are 101-009-009 (CR), 101-015-001 (CR), and 101-003-027 (PD). For efficacy analysis, submit a corrected BIOTR.xpt dataset that permits identification of the minimum post-treatment SPD and associated % change from baseline for all 96 IRC-evaluated patients in the mITT population for Period 1 only.

Please respond by May 25, 2017.

Please acknowledge receipt of this request!

Thank You

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