

## 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 MINSDFL=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

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)

"THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone."