

Davidson, Mark

From: Davidson, Mark
Sent: Monday, June 26, 2017 1:26 PM
To: 'Rizwana Sproule'
Cc: 'Nadia Agopyan'; 'Alex Babayan'
Subject: Kite Pharma BLA 125643 Clinical information request June 26, 2017

Dear Dr. Sproule,

We have the following request for additional clinical data:

Tumor measurements (ZUMA1):

- a) ADTR.xpt: Per the response to the April 28, 2017 information request, 98 of 101 mITT patients had post-baseline tumor burden values per investigator, including subject 101-017-001 who had progressive disease but missing lesion measurements. You indicated that the site was being queried to report these measurements. To permit an accurate waterfall plot, include these missing lesion measurements for subject 101-017-001, with an associated new "MINSPDFL" flag, in a revised ADTR.xpt file. By June 30, 2017, submit this revised ADTR.xpt file at the same time as all other datasets being submitted with an April/2017 cutoff.
- b) BIOTR.xpt: Per the response to the June 2, 2017 information request, subject 101-003-002 had nonmeasurable disease at Month 3, yet had an SPD reported as 0 resulting in an erroneous derived % change from baseline of -100% at that timepoint. You indicated that a correction had been requested.

By June 30, 2017, submit this revised BIOTR.xpt file at the same time as all other datasets being submitted with an April/2017 cutoff.

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

"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."