

Davidson, Mark

From: Davidson, Mark
Sent: Wednesday, July 05, 2017 10:08 AM
To: 'Rizwana Sproule'
Cc: 'Nadia Agopyan'; 'Alex Babayan'
Subject: Kite Pharma BLA 125643 Clinical Information request June 5, 2017

Dear Dr. Sproule,

The ZUMA1 ADTTE.xpt file submitted 7/3/2017 is missing the parameter of PFS sensitivity analysis (with censoring at time of SCT). For efficacy analysis, submit a revised ADTTE.xpt file that includes PFS sensitivity analysis per investigator and per IRC.

Submit this dataset by 12 pm EST, Thursday July 6, 2017.

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."