

Davidson, Mark

From: Davidson, Mark
Sent: Thursday, July 06, 2017 9:42 AM
To: 'Rizwana Sproule'
Cc: 'Nadia Agopyan'; 'Alex Babayan'
Subject: Kite Pharma BLA 125643 Statistical Information Request 7.6.17

Importance: High

Dear Dr. Sproule,

We have the following comments regarding DOR data in ZUMA1 ADTTE.xpt file

1. For the sensitivity analysis of DOR, subjects received SCT were censored at the last tumor assessment before SCT. Please provide an updated adtte.xpt with DOR censored at time of SCT for subjects received SCT, per investigator and per IRC.
2. In addition, we found the following issues regarding DOR per IRC in adtte.xpt. Please clarify and resolve these issues when submitting the updated adtte.xpt.
 - a. Subject KTE-C19-101-003-016: the last tumor assessment date was 06MAY2016 (per rs.xpt), however the censoring date in adtte.xpt was 06JUL2016.
 - b. Subjects KTE-C19-101-004-002 and KTE-C19-101-022-005: both received SCT but not censored in adtte.xpt.
3. Two subjects ('KTE-C19-101-003-006', 'KTE-C19-101-009-007') responded to KTE-C19, and died before disease progression. Please conduct a competing risk analysis for the DOR (with censoring at time of SCT), with the two non-relapse mortality as the competing risk.

Please respond by July 7, 2017

Thanks.

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."