From: Patel, Manisha
To: Giordano, Erica
Cc: Riggins, Cindy; Ahmed, Narin
Subject: RE: BL 125646 Statistical Information Request
Date: Tuesday, March 14, 2017 12:03:42 PM
Attachments: response-fda-03142017.pdf
Sensitivity: Confidential

Dear Erica,

Please find attached a response to FDA's request. I will submit a copy of this response through the gateway.

Kind regards,
Manisha

From: Giordano, Erica [mailto:Erica.Giordano@fda.hhs.gov]
Sent: Thursday, March 09, 2017 3:33 PM
To: Patel, Manisha
Cc: Riggins, Cindy; Ahmed, Narin
Subject: BL 125646 Statistical Information Request
Sensitivity: Confidential

Good afternoon,

Please see the following information request and provide a response by noon on March 14, 2017. If you need more time for the overall survival data please let me know and propose a timeline.

The analysis cut-off date is Nov. 23, 2016, however, a lot of the subjects were censored early, some were even censored in September. Please provide updated overall survival information, using the analysis cut-off date of Nov. 23, 2016 as the censoring date.

In addition, while reviewing your overall survival data, we note that UPN (b) (6) was listed as censored. There are no corresponding CRFs to review for this subject. Please review the submitted CRFs and data sets to assure that we have CRFs for all subjects in the analysis. Please explain the above discrepancy.

We found that several subjects had multiple disease response assessment outcomes on the same day in dataset ADEFIRC1. See the attached dataset multiple_assessment_on_same_day for the ids, assessment dates and outcomes for those subjects. It appears that the multiple outcomes are from two separate STDM data sources: SS and ZR. However the two data sets are not supposed to overlap, since SS was used when a subject discontinued the treatment and follow-up phase while ZR covered a subject's visits during follow-up. In addition, the disease response outcome does not seem to match with that from SS. Please clarify.

We noticed that six subjects have 'UNKNOWN' disease response assessment outcome at some follow-up visit(s). See the attached dataset unknown for the ids and assessment dates for those subjects. Please clarify whether 'UNKNOWN' means that the assessment was not carried out or the assessment was done but the result was uninterpretable.

Please confirm receipt of this request and that you were successfully able to open the attachments.

Thank you,

Erica Giordano
Regulatory Project Manager

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