

From: [Patel, Manisha](#)
To: [Giordano, Erica](#)
Cc: [Riggins, Cindy](#); [Ahmed, Narin](#)
Subject: RE: BL 125646 Statistical Information Request
Date: Monday, May 01, 2017 4:18:52 PM
Attachments: [image001.png](#)
[response-fda.pdf](#)
Sensitivity: Confidential

Dear Erica,

Please see attached response.

Kind regards,
Manisha

From: Giordano, Erica [mailto:Erica.Giordano@fda.hhs.gov]
Sent: Thursday, April 27, 2017 9:31 AM
To: Patel, Manisha <manisha.patel@novartis.com>
Cc: Riggins, Cindy <cindy.riggins@novartis.com>; Ahmed, Narin <narin.ahmed@novartis.com>
Subject: BL 125646 Statistical Information Request
Sensitivity: Confidential

Good morning,

Please see the information request below and provide a response by e-mail by noon on May 1, 2017 and follow up by submitting the information as an official amendment to the BLA.

We have difficulty verifying your subject disposition as shown in Table 2-1 of the summary of clinical efficacy 30-day efficacy update submitted on March 2nd. Table 2-1 shows that 68 subjects were infused. Among the subjects infused, 49 subjects have on-going follow-up and only 19 subjects have discontinued from the study follow-up. However, the DS.xpt dataset indicates that only 35 subjects (instead of 49) have on-going follow-up and more than 19 discontinued follow-up. Please clarify.

Please confirm receipt of this request.

Thank you,

Erica Giordano

Regulatory Project Manager
Center for Biologics Evaluation and Research
Office of Tissues and Advanced Therapies
U.S. Food and Drug Administration
Tel: 240-402-8298
Erica.Giordano@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 by e-mail or phone."