

**From:** [Wonnacott, Keith](#)  
**To:** [Giordano, Erica](#)  
**Cc:** [Riggins, Cindy](#); [Azevedo Santos, Joana](#)  
**Subject:** RE: BL 125646 Clinical Information Request  
**Date:** Monday, April 24, 2017 1:12:04 PM  
**Attachments:** [image001.png](#)  
[7008911\\_ANSW\\_MC\\_840\\_13.pdf](#)  
[Appendix 1.csv](#)  
**Sensitivity:** Confidential

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Erica,

Please see the attached files: one is an answer document and the other is the requested data in CSV format. We will follow up with a submission of this information through the gateway. If you have any questions, let me know.

Keith

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**From:** Giordano, Erica [<mailto:Erica.Giordano@fda.hhs.gov>]  
**Sent:** Wednesday, April 19, 2017 12:45 PM  
**To:** Riggins, Cindy  
**Cc:** Ahmed, Narin; Patel, Manisha  
**Subject:** RE: BL 125646 Clinical Information Request  
**Sensitivity:** Confidential

Yes T cell subsets of CD4+ and CD8+ T cells.

Subsets analysis = Immunophenotypes of T-cells as determined by flow cytometry, if at CD4/CD8 level if available.

I hope this helps, please let me know if you need anything else.

Erica

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**From:** Riggins, Cindy [<mailto:cindy.riggins@novartis.com>]  
**Sent:** Wednesday, April 19, 2017 11:19 AM  
**To:** Giordano, Erica  
**Cc:** Ahmed, Narin; Patel, Manisha  
**Subject:** RE: BL 125646 Clinical Information Request  
**Sensitivity:** Confidential

Hi Erica,

Can you clarify if by "CD4+/CD8+ ratio and subset analysis" in the question below, the subset analysis mean T cell subset analysis?

Thank you,

Cindy

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**From:** Giordano, Erica [<mailto:Erica.Giordano@fda.hhs.gov>]  
**Sent:** Tuesday, April 18, 2017 8:44 PM  
**To:** Riggins, Cindy; Patel, Manisha  
**Cc:** Ahmed, Narin  
**Subject:** RE: BL 125646 Clinical Information Request  
**Sensitivity:** Confidential

Thank you for confirming receipt.

This is a request from the clinical team. Please let me know if I can clarify anything else.

Erica

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**From:** Riggins, Cindy [<mailto:cindy.riggins@novartis.com>]  
**Sent:** Tuesday, April 18, 2017 5:18 PM  
**To:** Giordano, Erica; Patel, Manisha  
**Cc:** Ahmed, Narin  
**Subject:** RE: BL 125646 Clinical Information Request  
**Sensitivity:** Confidential

Dear Erica,

We confirm receipt. Can you clarify if this is a clinical or CMC request?

Thank you,

Cindy

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**From:** Giordano, Erica [<mailto:Erica.Giordano@fda.hhs.gov>]  
**Sent:** Tuesday, April 18, 2017 3:13 PM  
**To:** Patel, Manisha  
**Cc:** Riggins, Cindy; Ahmed, Narin  
**Subject:** BL 125646 Clinical Information Request  
**Sensitivity:** Confidential

Good afternoon,

In your BLA submission, you report on the CD4/CD8 ratio in the initial apheresis collection. You do not report it on the final product. Could you please provide the CD4+/CD8+ ratio and subset analysis for all of the final products with corresponding unique patient ID numbers. Please e-mail and electronic copy of the dataset in Excel by COB on April 24, 2017 and follow up by submitting the information as an amendment to the BLA.

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](mailto:Erica.Giordano@fda.hhs.gov)



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