

From: [Patel, Manisha](#)
To: [Giordano, Erica](#)
Cc: [Riggins, Cindy](#); [Ahmed, Narin](#)
Subject: RE: BL 125646 Pharmacometrics Information Request
Date: Wednesday, April 26, 2017 1:45:31 PM
Attachments: [image001.png](#)
Sensitivity: Confidential

Dear Erica, I confirm receipt of this request.

Kind regards,
Manisha

From: Giordano, Erica [mailto:Erica.Giordano@fda.hhs.gov]
Sent: Wednesday, April 26, 2017 1:40 PM
To: Patel, Manisha <manisha.patel@novartis.com>
Cc: Riggins, Cindy <cindy.riggins@novartis.com>; Ahmed, Narin <narin.ahmed@novartis.com>
Subject: BL 125646 Pharmacometrics Information Request
Sensitivity: Confidential

Good afternoon,

Please see the information request below and provide the information through e-mail by April 27, 2017 by COB and follow-up by submitting the information as an official amendment to the BLA.

Reference is made to your "Population cellular kinetics of tisagenlecleucel-T (CTL019) in pediatric and young adult patients with relapsed/refractory B-cell acute lymphoblastic leukemia (ALL)" modeling report.

Please submit all your model output files for the base and full models. The following files should be included:

1. Pop_parameters.txt
2. Predictions.txt
3. Results.mat
4. Indiv_parameters.txt
5. Indiv_eta.txt

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



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