

From: [Giordano, Erica](#)
To: [Patel, Manisha \(manisha.patel@novartis.com\)](#)
Cc: [Riggins, Cindy](#); [narin.ahmed@novartis.com](#)
Subject: BL 125646 Clinical Information Request
Date: Tuesday, August 15, 2017 8:11:52 AM
Attachments: [image001.png](#)

Good morning,

Please see the information request below and provide a response by noon today, August 15, 2017. Please provide the information directly in response to this e-mail and follow-up by submitting the information as an official amendment to the BLA.

Please provide the Subject ID numbers for all subjects on B2202 who received Bridging Chemotherapy as well as the type of Bridging Chemo that they received and start and stop dates. This should be for the Efficacy Set.

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."