

From: Dehdashti, Seameen (Jean)
To: ["jcastillo@portola.com"](mailto:jcastillo@portola.com)
Cc: [Gildner, Jean](#); [Giordano, Erica](#)
Subject: FDA Information Request (IR): BLA 125586
Date: Wednesday, December 27, 2017 7:41:00 PM
Attachments: [image001.png](#)
Importance: High

Good evening Janice,

FDA clinical review team is requesting the information outlined below. Please provide the requested information as a formal submission to BLA 125586 no later than 12:00 PM EST, Friday, December 29, 2017. In addition, please provide a courtesy replicate copy of your response by e-mail communication to all parties copied on this e-mail communication.

FDA Information Request:

- 1. Please update the ADSL table with 185 subjects to include information on the type of bleeding categorized as ICH, GI and other?**
- 2. Please provide the total number of subjects screened and enrolled in relation to the disposition of the 185 subjects in the safety evaluable population. Specifically, please clarify the reasons the number of subjects that were screened, enrolled to treat the 185 subjects. You may either reference the table or text in the clinical study report for Study 14-505 which has the information regarding screen failures, subjects who were enrolled but did not receive treatment. If such information is not available, please provide a table with the link to the table in your response.**

Please confirm receipt of this e-mail communication, and do not hesitate to contact me, should you have any questions and/or concerns.

Warm regards,

Jean Dehdashti, MSc, RAC
Regulatory Project Manager

Center for Biologics and Evaluation
Office of Tissues and Advanced Therapies
U.S. Food and Drug Administration
Tel: 240-402-9146
Seameen.Dehdashti@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.

