

## Dehdashti, Seameen (Jean)

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**From:** Dehdashti, Seameen (Jean)  
**Sent:** Monday, January 28, 2019 5:54 PM  
**To:** 'BDV (Barbara Davies)'  
**Cc:** Dehdashti, Seameen (Jean)  
**Subject:** FDA Information Request - Clinical: BLA 125671/0

**Importance:** High

Dear Barbara,

We are reviewing your BLA submission for Antihemophilic Factor (Recombinant), GlycoPEGylated, turoctocog alfa pegol (STN 125671), and have the following information request (IR), outlined below in **bold text**. There is no need to submit the requested information below as a formal amendment to the BLA; please send us your response via e-mail by close of business, Tuesday, January 29, 2019.

**FDA Information Request (IR) – Clinical:**

Please fill out the shaded boxes in the table below. This information is being requested to help FDA review team and management understand the difference in ABRs for the 65 subjects that were eligible for randomization in Ext 1 and chose not to be randomized, versus the 23 subjects who were ineligible for randomization. In addition, please send us the USID for the 23 subjects who were ineligible for randomization.

| Bleeding Outcome |                     | Extension 1 Phase (only)<br>(n=143)                |   |                                  |                                  |                                   |
|------------------|---------------------|--|---|----------------------------------|----------------------------------|-----------------------------------|
|                  |                     | Non-randomized<br>(n=88)                           |   |                                  | Randomized<br>(n=55)             |                                   |
|                  |                     | Q4 Day (Eligible<br>for<br>randomization<br>(n=65) | Q4 Day<br>(In-eligible for<br>randomization<br>(n=23) | All non-<br>randomized<br>(n=88) | Q4 Day<br>(Randomized)<br>(n=17) | Q 7 Day<br>(Randomized)<br>(n=38) |
| All bleeds       | Mean ABR<br>(SD)    |  |   |                                  | 1.68 (2.34)                      | 3.37 (6.19)                       |
|                  | Median<br>ABR (IQR) |  |   |                                  | 0.00<br>(0.00; 2.23)             | 0.00<br>(0.00; 2.36)              |

Please confirm receipt of this 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  
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