

From: Qian, Jiahua
To: "Ade_Denloye@baxter.com"
Cc: [Hooban, Christopher](#); [Maruna, Thomas](#)
Subject: FW: FDA Request for Info - Immune Globulin Subcutaneous (Human), 20% Solution - BL 125596/0 - Study 170904
Date: Tuesday, July 26, 2016 9:46:00 AM
Importance: High

Dear Ade,

We sent you three IRs last week. Please provide your response to last week's IR, COB today.

The following is the IRs we sent (combined) for your reference

"In Table 3, page 20 of 48 in the ISE, please clarify the number of 170904 subjects who were White, Black or African American, Hispanic, Asian and Multiple. The number appears to total 82 but the total number of enrolled subjects is listed as 77.

What the abbreviations "SCV" and "IVSCV" in Listing 30, Appendix 16.2.7 of study 170903 stand for.

For subject (b) (6) in study 170903, please ask the applicant to clarify the following discrepancy:

1. Page 694/737 of the CSR states subject (b) (6) was born in 2001.
2. Adverse Event Listings 5, 35 and 36 list the subject's age as 9 years. Since study 170903 began enrollment on 20 June 2011, how could he be 9 years of age?

Sent on behalf of LT Thomas Maruna

Our Reference: BL 125596/0

Baxalta US, Inc.
Attention: Ms. Aderonke Denloye
July 26, 2016
Sent by email

Thanks

Jiahua Qian Ph.D.
240 402 8432

From: Kelly, Sondag
Sent: Friday, July 22, 2016 1:16 PM
To: Denloye, Aderonke O (Ade_Denloye@baxter.com)
Subject: FDA Request for Info - Immune Globulin Subcutaneous (Human), 20% Solution - BL 125596/0 - Study 170904
Importance: High

Sent on behalf of LT Thomas Maruna

Our Reference: BL 125596/0

Baxalta US, Inc.
Attention: Ms. Aderonke Denloye
July 22, 2016
Sent by email

Dear Ms. Denloye:

We are reviewing your September 14, 2015 BLA for Immune Globulin Subcutaneous (Human), 20% Solution to treat primary immune deficiency disorders associated with defects in humoral immunity.

We determined that the following information is necessary to continue our review:

1. In Table 3, page 20 of 48 in the ISE, please clarify the number of 170904 subjects who were White, Black or African American, Hispanic, Asian and Multiple. The number appears to total 82 but the total number of enrolled subjects is listed as 77.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

Please submit your response to this information request as an amendment to this file by to this file *ASAP* referencing the date of this request.

The action due date for this file is September 13, 2016.

Sincerely,
Sonday L. Kelly, MS, RAC, PMP

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