

12_BLA 1255850_12 .txt

From: Sista, Ramani V
Sent: Tuesday, October 20, 2015 2:51 PM
To: 'Dr. Rebecca Haley'
Subject: BLA 125585/0,

Importance: High

Hi Dr. Haley,

Please provide the following information:

1. You state that the submitted data include (b) (4) units. However, several tabs in your excel file include (b) (4) records for cord blood units. Please clarify.
2. Please submit a new excel file including (1) patient ID; (2) cord ID; (3) TNC dose in 107/kg; (4) HLA match number 4, 5, or 6 in the form of 4/6, 5/6, 6/6. The submitted data should be able to replicate Table 5.3-6 and other relevant analyses.

Thanks,
Ramani

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