

From: Ocampo, Virginia  
Sent: Tuesday, March 27, 2018 6:30 PM  
To: Wilson,Jeffrey (jmwilson@mdanderson.org)  
Subject: BLA 125657 MD Anderson Cord Blood Bank\_ Biostatistics Information Request

Importance: High

Dear Jeff,

We have the following information request and kindly requests that you respond to us by April 3, 2018.

We cannot replicate the results reported in Table 2.6-1 of your “clinical-review” document (p.27 of 31), regarding platelet recovery to 50,000/uL. You reported the proportion of subjects with platelet recovery to 50,000/uL by Day 100 as 52.2%, and the median time to such recovery as 57 days. You also reported that 18 of the 846 subjects had missing data in these two variables. However, the “Intervaltoplatelet.50000days” variable has a value of “N/A TED” in 225 subjects, and a value of “” in 23 subjects. There is a total of 354 subjects with a “Yes” value for the “Platelet.50000” variable and a “Intervaltoplatelet.50000days” value less than or equal to 100 days. The “Platelet.50000” variable has 18 missing values. Therefore our calculation shows the proportion of subjects with platelet recovery to 50,000/uL by Day 100 to be  $354/(846-18) = 43\%$  with a 95% confidence interval of (39%, 46%). Excluding the 23 subjects with “” in the “Intervaltoplatelet.50000days” variable, and treating “NA TED” as potentially not recovering to 50,000/uL or a longer recovery time, the median time of platelet recovery to 50,000/uL is 65 days.

Please respond whether you agree with our results that (1) the proportion of recovery is 43% with a 95% confidence interval of (39%, 46%), and (2) the median time to recovery is 65 days. If you disagree with our calculation, please provide details in your calculation to enable replication.

Kindly acknowledge receipt.

Thank you,  
Virginia  
Virginia Ocampo, MT (ASCP)  
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