

Fax - RE: BLA125391 - PI, May 21, 2012 - HPC Cord Blood

From: Freed, Brian [Brian.Freed@ucdenver.edu]
Sent: Monday, May 21, 2012 2:53 PM
To: Sista, Ramani V; Miller, Sharon
Cc: Aubrey, Michael; Fan, Yong
Subject: RE: BLA125391 – PI

Attachments: FDA_PATIENT_TRANSPLANT_DATA_05212012.xls;
FDA_PATIENT_TRANSPLANT_DATA_05212012N64.xls; STN 125391 ClinImmune
Package insert Label V 5-18-12.doc; STN 125391 ClinImmune Package insert Label V
5-18-12_Clean.doc

Dear Ramani,

We looked at current outcome data (now up to 64 reports), and then looked at the first 47 by date of transplant. We came up with 77% male and 23% female with 34% infusion reactions in the first 47. However, the median age was 26 years (range 0.4-72). The difference may be due to the fact that we get new reports with data that may have been from a transplant performed much earlier, but only now reported. When we expanded the analysis to all 64 reports, the median age was 18. I've included an Excel spreadsheet of the first 47 and the current data with 64. In both instances, the infusion reactions were 34%.

It looks to me the data in the PI are accurate for the time they were submitted.

I've accepted the tracked changes and I'm sending back both versions.

Brian M. Freed, Ph.D., DABHI
Professor of Medicine and Immunology
Executive Director, ClinImmune Labs
12635 E. Montview Blvd, Suite 300
Aurora, CO 80045
303-724-0535

From: Sista, Ramani V [mailto:Ramani.Sista@fda.hhs.gov]
Sent: Sunday, May 20, 2012 7:38 PM
To: Freed, Brian; Miller, Sharon
Cc: Aubrey, Michael; Fan, Yong

Subject: RE: BLA125391 - PI
Importance: High

Hi Brian, Sharon,

Please see further changes made by our team and address the comment in the PI. Please respond back latest by 3:00 pm tomorrow.

Thanks,
Ramani

Thank you,

Ramani Sista, PhD, RAC
RPM
OCTGT/CBER/FDA
Phone: 301-827-5152

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From: Freed, Brian [mailto:Brian.Freed@ucdenver.edu]
Sent: Saturday, May 19, 2012 8:38 PM
To: Sista, Ramani V; Miller, Sharon
Cc: Aubrey, Michael; Fan, Yong
Subject: RE: BLA125391 - PI
Dear Ramani,

I'm returning both documents, and I've accepted the tracked changes in both. Although I suspect you only need the first one. Thank you for all your help and the help of the clinical team.

Brian M. Freed, Ph.D., DABHI
Professor of Medicine and Immunology

Executive Director, ClinImmune Labs
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303-724-0535

From: Sista, Ramani V [mailto:Ramani.Sista@fda.hhs.gov]
Sent: Friday, May 18, 2012 11:44 AM
To: Freed, Brian; Miller, Sharon
Cc: Aubrey, Michael; Fan, Yong
Subject: BLA125391 - PI
Importance: High

Hi Sharon, Brian,

Please see attached PI tracked and clean version with our edits. Please make your changes\edits in tracked and return the PI by noon Monday, EST. We have one comment for you to address.

Do let us know if you have questions or need clarifications.

Thanks,
Ramani

Ramani Sista, PhD, RAC
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