Record of Telephone Conversation, April 4, 2012 - ALLOCORD

Submission Type: BLA Submission ID: 125413/0 Office: OCTGT
Product:
Hematopoietic Progenitor Cells, Cord (HPC-C)
Applicant:
SSM Cardinal Glennon Children's Medical Center
Telecon Date/Time: 04-Apr-2012 01:00 PM Initiated by FDA? Yes
Telephone Number: -----(b)(4)-------
Communication Categorie(s):
1. Advice

Author: LEI XU
Telecon Summary:
Clinical and statistical related Information / Clarification
FDA Participants: Renee Reese, Lei Xu
Non-FDA Participants: Cathy Fortune, Hui Xu, Donna Regan
Trans-BLA Group: No

Related STNs: None
Related PMCs: None
Telecon Body:
The applicant was provided with the list of information / clarification from the joint clinical and statistical team prior to the scheduled teleconference. Please see below. The statistician from the applicant who did the initial analysis has left the applicant. The new statistician will review, clean-up and re-analyze the raw dataset, which was sent in the original BLA submission. The applicant will submit all information by April 26, 2012.

REVISED Information/Clarifications for St. Louis BLA 125413 (Cord Blood) Dataset

Please provide the following information.

1. One spreadsheet that contains all the data (not multiple sheets within one workbook). Please include one variable in the spreadsheet that uniquely identifies each patient.
2. A data dictionary (i.e., a definition of each variable in the spreadsheet).
3. In Patient Outcomes and Product Safety, section III (vii) of your application, you analyze data that is not available in the Excel spreadsheet containing the raw safety data set sent to the FDA on December 7, 2011 (e.g., HLA match). Furthermore, Table 31 of this section lists the number of patients analyzed for single and dual cord transplants as 1173 and 589, respectively, for a total of 1763 patients, but the Excel spreadsheet contains only 1211 units (rows). Please clarify which dataset was used in your analyses.

4. Data on HLA match.
5. Storage time or collection date information.
6. Manufacturing procedure used for each unit.
7. Are there any AE (adverse events) reported directly from physicians to the applicant?
8. Are all the units in the spreadsheets (including all the units for multiple unit recipients) manufactured by the St. Louis Cord Blood Bank?
9. Please clarify if the applicant has the SOPP regarding SAE report to the FDA. If yes, please submit for review.

Please clarify the following information in the dataset.

10. Patient with CIBMTR ID 176950 has a death date of (b)(6), one day earlier than the last contact date of (b)(6).
11. Patient with CIBMTR ID 2980581 has a death date of (b)(6), two days earlier than the infusion date of (b)(6).
12. "Infused Nucleated Cell Count" ≤ "Total Infused Nucleated Cell Count" for many single unit recipients. Please clarify the difference between these variables.
13. One patient (CIBMTR ID 64552) achieved neutrophil recovery ("ANC 500" is 'Y'), but is missing the number of days to recovery (DAYS to ANC 500).
14. Please clarify the distinction between a response of 'N' and 'Never' for the variable "ANC 500".
15. One patient (CIBMTR ID 190555) has a response of 1122 for "Days to ANC 500" and another (CIBMTR ID 205890) has 181 days; please confirm these large number of days.
16. 15 patients have a 'Y' response for "Platelets 50000", but are missing the number of days to recovery ("Days to Platelet 50,000").
17. 16 patients have a 'Y' response for "Platelets 20000", but are missing the number of days to recovery ("Days to Platelet 20,000").
18. What does a response of "U" represent for the variable "Platelet 50,000"?