Telecon, May 31, 2011 - HPC Cord Blood

RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125391/0 Office: OCTGT
Product:
Hematopoietic Progenitor Cells,Cord (HPC-C)
Applicant:
Clinimmune Labs
Telecon Date/Time: 31-May-2011 01:30 PM Initiated by FDA? Yes
Telephone Number: 303-724-0115
Communication Categorie(s):
1. Information Request

Author: RAMANI SISTA
Telecon Summary:
Clinical and Statistical Team had requests for information
FDA Participants:
Rachel Witten
Donna Przepiorka
Chunrong Chen
Ramani Sista

Non-FDA Participants:
Sharon Miller
Brian Freed

Trans-BLA Group: No

Related STNs: None
Related PMCs: None
Telecon Body:
Following introductions, the clinical team informed the Sponsor, that some elements were missing in their submission, which is essential for filing of their application. A list of deficiencies was emailed to the Sponsor prior to the tcon.

1. Please provide the following information or identify were the following information located in the submission:

a. This product may be subject to the Pediatric Research Equity Act and if the data to support intended indications do not cover all pediatric age groups (including neonates), you need to include in your submission a request for a waiver or deferral of the pediatric assessment.

Summary of Discussion: The Sponsor stated that chords are infused in children less than a year old and requested clarification regarding FDA requirement. FDA explained that PREA covers all children including neonates and preterm. The Sponsor is required to submit a waiver for each of the 7 indications that neonates are usually not treated for. This waiver is a request to waive clinical studies in neonates and could be a short letter outlining the request.

b. Copy of data set used for your safety outcome analysis. The data set must be submitted as a SAS transport file.

Summary of Discussion: FDA asked the Sponsor if they had a dataset, the Sponsor replied that they could provide an Excel sheet, but were not familiar with SAS. FDA stated that Excel spreadsheet was acceptable.

c. SOP for elicitation and handling of post donation information

Summary of Discussion: The Sponsor stated that the post donation information is in the consent form. FDA indicated that was not sufficient. An SOP covering the entire process was requested.

d. SOP for elicitation and handling of recipient adverse events

Summary of Discussion: The Sponsor stated that they have 2 SOPS associated with infusion and product and they would email the information to FDA.

e. SOP for notification of mothers or their responsible physicians of positive or indeterminate test results according to local or national regulations

Summary of Discussion: The Sponsor stated that this SOP was included in the submission.

f. Validation of physician training materials

Summary of Discussion: The Sponsor stated that they conduct internal audits -- (b)(4)-- to see if training is working and agreed to provide the latest audit report.

g. Please clarify if B5.100.4 is your plan for assessment of clinical outcome data in the post marketing period

Summary of Discussion:
Sponsor indicated that a number of SOPs covers the plan, and they would submit the list.