

FDA Required List Email, September 29, 2011 - Ducord

From: Zhu, Yao-Yao
To: "kurtz001@mc.duke.edu";
cc: Przepiorka, Donna; Davidson, Mark;
Subject: RE: FDA required list
Date: Thursday, September 29, 2011 3:43:04 PM

Dear Dr. Kurtzberg,

As per our T'con discussion at 10 AM today, please see following list of FDA required variables for your cord blood BLA. Please submit all required datasets within a week (not more than 2 weeks) so we can initiate our review process as soon as possible.

List of minimal requirement of variables on the Cord-blood BLA data sets:

Data on the cord blood units should include at a minimum,

- the recipient ID
- unit ID
- degree of HLA mismatch
- recipient weight
- TNC dose and TNC/kg dose at cryopreservation
- processing method
- date stored
- date transplanted
- donor ineligibility reason (if any)
- reaction to infusion.

Data on the patients transplanted should include at a minimum

- the recipient ID
- age (in days) or date of birth
- gender
- race/ethnicity
- diagnosis
- transplant date
- TCBB IDs of cord blood units transplanted
- total number of units (TCBB plus nonTCBB units) transplanted
- total TNC/kg (at cryopreservation)
- degree of HLA mismatch (worst degree for multiple unit transplants)
- date of neutrophil recovery
- date of platelet recovery
- graft failure (primary or secondary)
- date censoring for competing risks of engraftment (autologous recovery, boost or second transplantation, relapse)
- maximum grade of acute GVHD
- date of last follow-up

date of death
cause of death

Any additional variable that you used in the analyses submitted or that will assist in the evaluation of the safety of the product.

Thank you! Yao-Yao Zhu, Clinical Reviewer

Yao-Yao Zhu, MD, PhD

Medical Officer, Division of Clinical Evaluation and Pharmacology/Toxicology Review

Office of Cellular, Tissue, and Gene Therapies

Center for Biologic Evaluation and Research

Food and Drug Administration

e-mail: yao-yao.zhu@fda.hhs.gov

Tel: (301)827-9141

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

Yao-Yao Zhu, MD, PhD

Page Last Updated: 02/21/2017

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Language Assistance Available: [Español](#) | [繁體中文](#) | [Tiếng Việt](#) | [한국어](#) | [Tagalog](#) | [Русский](#) | [ةيبرعلا](#) | [Kreyòl Ayisyen](#) | [Français](#) | [Polski](#) | [Português](#) | [Italiano](#) | [Deutsch](#) | [日本語](#) | [عسراف](#) | [English](#)