

From: [Smith, Liz](#)
To: [Tull, Lori](#); [Kim, Helen](#);
Subject: Re: Registry Study
Date: Wednesday, March 10, 2010 1:46:08 PM

1500.

From: Tull, Lori <Lori.Tull@fda.hhs.gov>
To: Kim, Helen
Cc: Smith, Liz
Sent: Wed Mar 10 10:44:32 2010
Subject: RE: Registry Study

Hi Helen,

Would please also provide us with the number of subjects you will include in the registry. Can you provide that information by tomorrow?

Lori

Lori A. Tull, RAC
Regulatory Project Manager
Office of Cellular, Tissue, and Gene Therapies
Center for Biologics Evaluation and Research
(301) 827-5359

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.

From: Kim, Helen [mailto:hkim@Dendreon.com]
Sent: Tuesday, March 09, 2010 5:40 PM
To: Tull, Lori
Cc: Smith, Liz
Subject: Registry Study
Importance: High

Lori –

Per our PVP teleconference call last week on March 4, 2010, below are our responses to the questions posed regarding the Registry:

1. The date when the final Registry study protocol will be submitted = **June 30, 2010**
2. The date when the final Registry study will be completed = **December 31, 2015** (complete 3 year follow-up on all patients)
3. The date when the final study report will be submitted = **September 30, 2016**

Please confirm that the Registry will be considered a **“study** and not a “trial as defined in the FDA Draft Guidance for Industry entitled, *Postmarketing Studies and Clinical Trials – Implementation of Section 505(o) of the Federal Food, Drug, and Cosmetic Act (July 15, 2009)*.

Helen Kim
Director, Regulatory Affairs
Dendreon Corporation
(W) 206.829.1464
(C) 206.227.8893
(F) 206.441.4070
hkim@dendreon.com

This email message including any attachments is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original message. If you are the intended recipient, please be advised that the content of this message is subject to access, review and disclosure by the sender's Email System Administrator.

This email message including any attachments is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply

email and destroy all copies of the original message. If you are the intended recipient, please be advised that the content of this message is subject to access, review and disclosure by the sender's Email System Administrator.

