

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

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1500.

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**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

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Please confirm that the Registry will be considered a **“study** and not a “trial as defined in the FDA Draft Guidance for Industry entitled, *Postmarketing Studies and Clinical Trials – Implementation of Section 505(o) of the Federal Food, Drug, and Cosmetic Act (July 15,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