

# Request for information, February 24, 2011 - Laviv

From: Tull, Lori  
Sent: Thursday, February 24, 2011 2:34 PM  
To: 'Dana Weinberger'  
Subject: RE: Request for information

Thanks Dana.

One more issue regarding to that SAE case: We would like the you to provide your rationale as why you consider this SAE (leukocytoclastic vasculitis) is unlikely to be related to the study product.

Thanks,

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: Dana Weinberger [mailto:dweinberger@cbrintl.com]  
Sent: Wednesday, February 23, 2011 5:06 PM  
To: Tull, Lori  
Cc: Dana Weinberger; Jeanne Novak  
Subject: RE: Request for information

Dear Lori,

Thank you for your request. We are working with the clinical site and hospital to obtain the requested information, and we will provide you with any available information as soon as possible. We currently are expecting to submit available information the week of Feb 28th, and we will keep you posted regarding any change to this timeline.

Please feel free to let us know if you have any questions or requests, or need the information more urgently.

Thanks,

Dana

Dana A. Weinberger, Ph.D., RAC  
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From: Tull, Lori [mailto:Lori.Tull@fda.hhs.gov]  
Sent: Friday, February 18, 2011 10:19 AM  
To: Jeanne Novak  
Cc: Dana Weinberger; Kevin Hennegan  
Subject: Request for information

Hi Jeanne,

Dr. Zhu would like to request the following information regarding subject --(b)(6)- who had SAE of leukocytoclastic vasculitis in Study IT-H-001.

- (1) full admission history & physical and discharge summary of the July 4 admission;
- (2) rheumatological and/or dermatological consultation write-ups;
- (3) skin biopsy report on the admission;
- (4) routine blood work, lab tests, and rheumatological markers during this admission: such as CBC, CMP, UA C&S, CRP, ESR, ANA, ANCA, etc;
- (5) clinical follow-up and update on this patient, including any blood work such as CRP/ESR (whether it is normalized)

Thank you,  
Lori

Lori A. Tull, RAC  
Regulatory Project Manager  
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Page Last Updated: 07/19/2011

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