

Question for Fibrocell Email, May 12, 2011 - Laviv

From: Tull, Lori
Sent: Thursday, May 12, 2011 8:50 AM
To: 'Dana Weinberger'
Subject: RE: Question for Fibrocell

Thank you!

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, May 11, 2011 10:11 PM
To: Tull, Lori
Cc: Jeanne Novak; Dana Weinberger
Subject: FW: Question for Fibrocell

Dear Lori,

Across all six studies described in Table 2 of Amendment 39, there was a total of 158 subjects treated. IT-G-003 was a follow-on study, in which 12 of the 20 subjects from IT-G-002 were enrolled. Also, IT-H-001 enrolled 16 subjects who previously participated in IT-A-008. (Note: the other 13 subjects in IT-H-001 previously participated in IT-R-005 and IT-R-006, not discussed in the table.) The difference between 186 and 158, 28, is accounted for by the sum of the 12 subjects who participated in both IT-G-002 and IT-G-003, and the 16 subjects who participated in both IT-A-008 and IT-H-001.

We have reported the numbers consistently with this approach throughout Amendment 39, so we do not feel that any revisions are required. We hope that this explanation is helpful.

Please feel free to contact me or Jeanne Novak with any questions or requests.

Thanks,
Dana

Dana A. Weinberger, Ph.D., RAC

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From: Tull, Lori [mailto:Lori.Tull@fda.hhs.gov]
Sent: Wednesday, May 11, 2011 12:16 PM
To: Jeanne Novak; Dana Weinberger
Subject: FW: Question for Fibrocell

Hi Jeanne and Dana,

We have a question regarding Amendment 39 below.

"For Amendment 39, page 5 of 16, Table 2, total number of subjects seems to be 186 instead of 158. Please clarify this number and correct all calculation of AE in all the Tables that may be affected."

Best Regards,

Lori

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