

Request for Clarification Email, March 15, 2011 - Laviv

From: Jeanne Novak [jnovak@cbrintl.com]
Sent: Tuesday, March 15, 2011 6:14 PM
To: Tull, Lori
Cc: Dana Weinberger; Jeanne Novak
Subject: RE: Request for clarification

Importance: High

Attachments: emfalert.txt

Dear Lori,

Dana and the team looked into this issue and determined that the table you sent over seems to be misaligned between the subject ID number and the treatment assignment columns . We can send you a fax or pdf showing how these should be aligned (one row off). In short, -(b)(6)- did receive azficel-T in IT-R-006.

Let us know if you would like to have us send the annotated document back to you.

Jeanne and Dana

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From: Tull, Lori [mailto:Lori.Tull@fda.hhs.gov]
Sent: Monday, March 14, 2011 8:27 AM
To: Jeanne Novak; Dana Weinberger
Subject: Request for clarification

Hi Jeanne and Dana,

Would you please help us clarify the following:

Subject -(b)(6)- received Placebo (see Table below in red ink) during study 006 according the assignment chart below; however, you stated that the subject received three treatments of azficel-t instead of placebo in study 006 in Amendment 35 (see paragraph on page 6 of amendment 35 below in red ink).

"On 25 June 2010 the subject received 0.2 mL azficel-T intradermally in his right arm and 0.2 mL placebo (saline) in his left arm as part of the Fibrocell IT-H-001 clinical study. (Note: Previously, subject had received three treatments, five weeks apart of 1.15 mL azficel-T to his face for the treatment of nasolabial fold wrinkles in 2007 as part of the Fibrocell IT-R-006 clinical study)".

ASSIGNMENT PATIENT IDENTIFICATION NUMBER LOCATION

(b)(6)
------(b)(6)-----
Placebo

(b)(6)
------(b)(6)-----
IT

(b)(6)
------(b)(6)-----
Placebo

(b)(6)
------(b)(6)-----
Placebo

(b)(6)
------(b)(6)-----
IT

(b)(6)
------(b)(6)-----
IT

(b)(6)
------(b)(6)-----

IT

(b)(6)
-----~~(b)(6)~~-----
Placebo

(b)(6)
-----~~(b)(6)~~-----
Placebo

(b)(6)
-----~~(b)(6)~~-----
IT

(b)(6)
-----~~(b)(6)~~-----
Placebo

(b)(6)
-----~~(b)(6)~~-----
N/A

(b)(6)
-----~~(b)(6)~~-----

N/A

(b)(6)
-----~~(b)(6)~~-----

N/A

(b)(6)
-----~~(b)(6)~~-----

N/A

IT-R-006
6600
Placebo
(b)(6)
-----~~(b)(6)~~-----

Placebo
(b)(6)
-----~~(b)(6)~~-----

Placebo
(b)(6)
-----~~(b)(6)~~-----

Placebo
(b)(6)
-----~~(b)(6)~~-----

IT
(b)(6)
-----~~(b)(6)~~-----

IT
(b)(6)
-----~~(b)(6)~~-----

IT
(b)(6)
-----~~(b)(6)~~-----

Placebo
(b)(6)
-----~~(b)(6)~~-----

Placebo
(b)(6)
-----~~(b)(6)~~-----

IT
(b)(6)
-----~~(b)(6)~~-----

IT
(b)(6)
-----~~(b)(6)~~-----

IT
(b)(6)
-----~~(b)(6)~~-----

Placebo
(b)(6)
-----~~(b)(6)~~-----

Lori A. Tull, RAC
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