

Clarification regarding AE tables Email, October 05, 2009 - Laviv

From: Jeanne Novak [jnovak@cbrintl.com]
Sent: Monday, October 05, 2009 4:43 PM
To: Haudenschild, Changting
Cc: Tull, Lori; Dana Weinberger; Jeanne Novak
Subject: Clarification regarding AE tables

Importance: High

Dear Changting,

As you know, we originally emailed draft tables regarding rare (<1%) related adverse events to Dr. Zhu on 9/30/09, and we emailed revised, final versions to Dr. Zhu on 10/2/09. We also made a formal submission (BLA 125348; Amendment 13) of these AE tables for delivery to the document control room tomorrow.

You also emailed draft slides that you prepared on this topic on Oct. 1st, and we discussed the impact of changes made to the tables on the draft slides by phone on Oct. 2nd. Further to the discussion on Oct. 2nd, we wanted to note that the following changes were made to Table 1: events for the preferred terms erythema, post procedural dizziness, and post procedural headache were added to the final version relative to the original draft version. Only the event of post procedural headache occurred in Studies IT-R-005 or IT-R-006 (the other two did not occur in these studies). Post procedural headache was reported for subject -b(6)-. As such, we think that the addition of the event of post procedural headache may have an impact on the draft slides regarding AEs in Studies IT-R-005 and IT-R-006 that you provided.

We hope this information helps your review. Please feel free to contact me with any questions or requests.

Best regards,

Jeanne

Jeanne M. Novak, Ph.D.
Owner and Principal Consultant
CBR International Corp.
720-746-1190
720-746-1192 (Fax)
www.cbrintl.com

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