

From: kate dawson/cambridge/biogenidec;nsf;kate.dawson@biogenidec.com;smt
Sent: Mon Jul 17 2006 08:10:11 EDT
To: ratna lingamaneni/cambridge/biogen@biogenidec;
CC: gilmore o'neill/cambridge/biogen@biogenidec;minhua yang/cambridge/biogen@biogenidec;tammy sarnelli/cambridge/biogen@biogenidec;
Subject: Re: EOP2 document- Safety data from C1900

Summarizing for the group after several conversations/emails.

Gilmore has rewritten/editted Section 7 and will be sending it to me later today.

We agree that a summary of the data/rationale from the Response to Clinical Hold should be included, and that a link to the full submission established so that FDA can (re)review in detail.

Safety data should be presented in tables as is possible, and we understand that the psoriasis exposure safety table will not be available prior to publishing tomorrow, but we hope to have it later this week.

C-1900 safety data and tables should either describe blinded and safety extension phases separately OR blinded and then overall.

Rationale for testing/safety monitoring in the Ph 3 trials (ie cardiac, liver, no esophago-gastroscopy) should be tied to the data.

Please correct if these assumptions are not correct.

Kate

Ratna Lingamaneni/Cambridge/Biogen
07/17/2006 08:42 AM
Message Size: 15.8 KB

To
Kate Dawson/Cambridge/Biogen@BiogenIdec
cc
Gilmore O'Neill/Cambridge/Biogen@BiogenIdec, Minhua Yang/Cambridge/Biogen@BiogenIdec, Tammy Sarnelli/Cambridge/Biogen@BiogenIdec
Subject
Re: EOP2 document- Safety data from C1900

Hi Kate,

I think that we have the AE tables available for total BG12 experience - a draft version was included in the IND clinical hold response, that was later updated following the database lock. I guess we could include them in the document if they are readily available.

-Ratna

Kate Dawson/Cambridge/Biogen
07/17/2006 08:07 AM
Message Size: 13.2 KB

To
Ratna Lingamaneni/Cambridge/Biogen@BiogenIdec
cc
Gilmore O'Neill/Cambridge/Biogen@BiogenIdec, Minhua
Yang/Cambridge/Biogen@BiogenIdec, Tammy Sarnelli/Cambridge/Biogen@BiogenIdec
Subject
Re: EOP2 document- Safety data from C1900

I will check with Gilmore regarding this section and authoring. When this information is included, do we just need to:

write about the extension phase in text, or
re-run the 5% AE table with all data, or
have separate and combined tables?

Do these already exist in the C1900 CSR?

Kate

Ratna Lingamaneni/Cambridge/Biogen
07/17/2006 07:32 AM
Message Size: 10.7 KB

To
Minhua Yang/Cambridge/Biogen@BiogenIdecc
cc
Kate Dawson/Cambridge/Biogen@BiogenIdecc, Gilmore
O'Neill/Cambridge/Biogen@BiogenIdecc, Tammy Sarnelli/Cambridge/Biogen@BiogenIdecc
Subject
Re: EOP2 document- Safety data from C1900

Hi Minhua,

At the last review meeting (on July 7th) this issue was discussed and it was agreed to update the safety section to include the information from both part 1 and 2 of the study in the package for completeness. I believe that Gilmore is working on this for the next version.
-Ratna

Minhua Yang/Cambridge/Biogen
07/14/2006 04:31 PM
Message Size: 1472.1 KB

To
Ratna Lingamaneni/Cambridge/Biogen@BiogenIdecc
cc
Kate Dawson/Cambridge/Biogen@BiogenIdecc
Subject
Re: EOP2 document- 1 comment

Hi Ratna:

I don't know if I have the most recent version of the briefing document, but in the doc you sent me below, on Pag 51-52, we need to make it clear we are only discussing data for the placebo-controlled phase. For example, On page 52 2nd paragraph, when we say " 7/256 subjects withdrew fromt eh study, it is only referring to the part 1 placebo-controlled phase.

-minhua

Ratna Lingamaneni/Cambridge/Biogen
07/06/2006 03:44 PM
Message Size: 1469.5 KB

To
Minhua Yang/Cambridge/Biogen@BiogenIdec
cc

Subject
Re: EOP2 document

Hi Minhua,

Sure, enclosed is the current version that was distributed to the cross-functional team. Tomorrow we are having a review meeting (2 - 3PM, room 741) to go over the comments, let me know if you could attend.

[attachment "EOP2 Meeting Package Second Publishing June 28 2006.pdf" deleted by Ratna Lingamaneni/Cambridge/Biogen]

-Ratna

Minhua Yang/Cambridge/Biogen
06-Jul-2006 03:39 PM
Message Size: 1.6 KB

To
Ratna Lingamaneni/Cambridge/Biogen@BiogenIdec
cc

Subject
EOP2 document

Hi Ratna:

Will you please include me in the EOP2 document emails? Thanks.

-minhua