

Follow-up re Reformatting of Integrated Datasets Email, July 9, 2009 - Laviv

From: Jessica Allmond [jallmond@cbrintl.com]

Sent: Thursday, July 09, 2009 11:54 AM

To: Tull, Lori

Cc: Jeanne Novak

Subject: Isolagen BLA STN 125348 - Follow-up re Reformatting of Integrated Datasets

Importance: High

Dear Lori,

As we discussed via telephone this morning, would it be possible to forward the questions below to the individual at the FDA (named Amy per Shiowen Lee) who originally requested the reformatting of the integrated datasets? Your assistance with this matter is greatly appreciated.

BACKGROUND:

During an informal call on 08 July 2009, the FDA stated that the individual study datasets Isolagen provided from Studies IT-R-003A/B and IT-R-005/006 are "fine" but the datasets used for the integrated analysis are not because they are in a "different" format (SDTM) which they cannot readily use. The Agency requested Isolagen provide the integrated analysis datasets in the same format as the individual study datasets as soon as possible. After further discussions with Isolagen's statistician and the FDA reviewers, Isolagen has some questions and an alternative proposal for the Agency's consideration. Hopefully, the proposal will be acceptable in meeting the FDA's needs as this alternative is more readily available and can be implemented much faster than reformatting the entire integrated datasets. Isolagen is committed to doing everything possible to address this information request quickly. Thank you very much in advance for your consideration and feedback on the questions and proposal below.

QUESTIONS AND PROPOSAL:

1. The FDA reviewers have stated that they are able to use the individual study datasets Isolagen provided from Studies IT-R-003A/B and IT-R-005/006 and that these datasets are already in an acceptable format. If these individual datasets are known to work with the Agency's software and can be used for the FDA's required analyses using this software, would an acceptable alternative, to Isolagen re-formatting the integrated datasets, be for Isolagen to submit as a BLA amendment the individual study datasets not provided with the original BLA (i.e., R001, R002, and R007)?
2. If the proposal above is not an acceptable alternative, can the Agency please provide some filenames from the individual study datasets that are in the desirable format as examples so that we have a better idea of the format needed for the integrated datasets? The FDA reviewers have stated that the individual study datasets provided from Studies IT-R-003A/B and IT-R-005/006 are in an acceptable format.

3. Additionally, if the proposal above is not an acceptable alternative, can the Agency please provide the filenames of the integrated datasets that are deemed critical for reformatting in support of the FDA's review? Clarification if Isolagen would only need to reformat a subset of the integrated datasets would be extremely helpful.

Again, thank you Lori for your assistance. Should the Medical Division have any follow-up questions, or if the Agency would like further discussion, please do not hesitate to contact Dr. Jeanne Novak (Isolagen's Authorized Regulatory Representative) or myself in her absence.

Kind regards,

Jessica Allmond, M.A.S., RAC

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