

Susanne Lee /AM/LLY

12/22/2010 11:15 AM

To David G Perahia/EMA/LLY@Lilly

cc

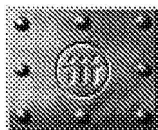
bcc

Subject Re: Question on DEAEs

Thanks David. That is interesting about the placebo patients.

Take care,
Susanne

David G Perahia/EMA/LLY



David G Perahia /EMA/LLY

12/22/2010 10:39 AM

To Susanne Lee/AM/LLY@LILLY

cc

Subject Re: Question on DEAEs

Hi Susanne,

I'm around - not on vacation until Friday p.m.

I'm not aware that we systematically collected further information on those patients whose DEAEs hadn't resolved prior to the final contact. You're right that more than 50% of patients who experienced a DEAE after stopping duloxetine reported that their DEAEs were unresolved at the final contact. Interestingly, however, this was also the case for patients who reported DEAEs after discontinuing placebo treatment - more than 1 in 5 placebo-treated patients in the acute studies examined in the manuscript reported at least one DEAE on discontinuation of placebo, and of these patients more than 50% reported that their DEAEs were unresolved at the final contact.

Best wishes,

David.

Susanne Lee/AM/LLY

Susanne Lee /AM/LLY

22/12/2010 15:09

To David G Perahia/EMA/LLY@Lilly

cc

Subject Question on DEAEs

Hi David,

I hope you are enjoying your time off and having a wonderful holiday! I wanted to send this email off to you before I forget...I was speaking with a physician today who was having trouble with DEAE in a patient of his. I spoke from your DEAE manuscript re: onset and duration of the symptoms. Part of the issue was that he was "tapering" by having his patient take a 30 mg dose every 3rd day, and her symptoms would start

around day 2. So he hasn't really tried to let her come off of it. From the manuscript, it seems like the DEAEs were allowed to run their course. His concern was that, if only overall 45.1% of DEAEs were resolved prior to final contact, what was the outcome of the other 50+% of patients? I told him I'd follow-up and see if any of our CRPs would know...but did explain that we may not have that data since our lead-out period for collection of DEAEs was 1-2 weeks. Do you have any wisdom to share with me on this one? :D

Thanks!!
Susanne