

Jureidini, Jon (Health)

From: John Kraus <john.e.kraus@gsk.com>
Sent: Thursday, 20 November 2014 23:39
To: Jureidini, Jon (Health)
Cc: James Shannon
Subject: RE: Reply to Dr Kraus

Dear Professor Jureidini,

Thank you for your letter dated 12 November 2014 and your additional questions.

In my earlier response I answered your original question about evidence that the HAM-D depression item was identified before breaking the blind. As I have previously mentioned, this is stated in both the paper and the clinical study report and the file note documentation I sent reaffirms this. At the time study 329 took place, analytical plans included the Reporting and Analysis plan document as well as other communications reflecting the intentions of the external investigators and study statisticians.

As with the HAM-D depression item, the paper and clinical study report state that the other secondary endpoints you have asked about were also identified before breaking the blind. I have no reason to believe that plans to analyze these endpoints were different to the HAM-D depression item.

Clearly you should conduct your analyses as you believe appropriate and I look forward to the completion of your work and the publication of your paper.

Kind regards,

John

John E. Kraus, MD, PhD, DFAPA
VP, Medicines Development Leader

-----Original Message-----

From: Jureidini, Jon (Health) [<mailto:Jon.Jureidini@health.sa.gov.au>]
Sent: Tuesday, November 11, 2014 9:21 PM
To: John Kraus
Cc: James Shannon
Subject: RE: Reply to Dr Kraus

Dear Dr Kraus

Please find a letter containing some further questions.
Looking forward to your reply.
Jon Jureidini