

Greg Clarke (503) 335-6673,3/30/99 3:45 PM +0000,Feedback on Paroxetine Ac 1

MR-Received: by eta TABOR; Delayed; Tue, 30 Mar 1999 16:06:27 +0000
MR-Received: by eta KPBMCA; Delayed; Tue, 30 Mar 1999 16:08:25 +0000
Alternate-recipient: prohibited
Date: Tue, 30 Mar 1999 15:45:14 +0000 (GMT)
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Subject: Feedback on Paroxetine Acute Phase Efficacy manuscript
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Cc: Kelly Griffin <Kelly_Griffin@brown.edu>
MIME-version: 1.0
Posting-date: Tue, 30 Mar 1999 16:07:00 +0000 (GMT)
Importance: normal
Priority: normal
X1-type: MAIL
Hop-count: 2

Please find below my feedback on the 3/22/99 draft of the Paroxetine Acute Phase Efficacy manuscript. I rec'd the draft yesterday (3/29), but the cover memo from Dr. Keller was dated 2/22/99 and asked for feedback within two weeks. I hope this isn't too late. Ms. Griffin - I hope you can forward this feedback to Dr. Keller.

By and large, the MS reads fine. The first two comments below are minor editorial suggestions; the latter comments are more important (but still ignorable):

- 1. Numbers less than ten should usually be spelled out (one, two, etc.)
2. JAMA uses a numbered citation style - I presume this will be changed later.

(see this website for instructions:

http://www.ama-assn.org/public/journals/jama/instruct.html

3. There are quite a few depression dependent variables - although the analyses were pre-planned, it still seems odd that the alpha is not adjusted for the large number of comparisons - e.g., a Bonferroni correction. Obviously this would lessen the significance of the findings, but it is probably more conservative.

4. Page 15 - first paragraph, second sentence should be re-written as "Using effect size data from adult depression treatment studies (citation?), a sample size of 300 subjects (later modified to 275) was determined a priori as the target recruitment needed to detect a difference between active treatments and placebo conditions."

5. Page 16 - first sentence of Results - the statement that 425 were screened and 275 were enrolled is redundant with study design description at the bottom of page 7 - Decide on one location or the other and eliminate the redundant statement.

6. Page 16, first paragraph, last sentence - add the following to the front of that sentence "Despite the exclusion criteria limiting many comorbidities, ..."

7. The MS makes the point several times that subjects withdrew at high rates from IMI because of adverse effects - perhaps mentioned once too often. It is an important finding, but because the statement appears three? four? times it appears a bit partisan. It doesn't need to be noted so often.

My last question has to do with contributors to the study other than the lead investigator at each site. Two child psychiatrists at Oregon Health Sciences University, William Beck, M.D. and Nancy Winters, M.D., donated much of their time to the medication treatment sessions in hopes of some acknowledgement on MSs. I imagine that the same situation exists at other sites. Can they be added to an acknowledgement list? Thanks, GREG

Sally! please do this!!
since comparisons were a mini-2
Do not rank order
is necessary
Wed?
Thu?
Fri?
Sat?
Sun?
Suggest dismissed by Keller.

agreed

ok

ok

OK - Experiment 6 -
see page 6 -
I have
sent a
request to all
sites to provide
names of people
to be
acknowledged

Printed for "Kelly A. Griffin" <Kelly_Griffin@Brown.edu>

Some of Sally Winters