

**From:** OC GCP Questions  
**To:** [REDACTED]  
**Subject:** RE: A Study in the Treatment of Children and Adolescents With Major Depressive Disorder  
**Date:** Wednesday, August 26, 2015 3:01:00 PM

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Good Afternoon,

Thank you for contacting FDA with your question. Although the trials you reference in your e-mail appear to be identical, close inspection of the information in the ClinicalTrials.gov record and the publications indicate that these appear to be separate trials. For example, the dosing strategy for the two trials appears to be different, as does the site locations for the two trials.

Duplication of trials can occur on ClinicalTrials.gov, in some cases due to user error. In the future, should you find an example of the identical trials with differing NCT numbers, please contact the ClinicalTrials.gov staff to see if they can reconcile the discrepancy. They may be contacted at [NLM Helpdesk](#).

I hope this information is helpful. Please contact us again at [gcp.questions@fda.hhs.gov](mailto:gcp.questions@fda.hhs.gov) should you have additional questions.

Patrick J. McNeilly, Ph.D., C.I.P.  
Office of Good Clinical Practice  
Food and Drug Administration

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

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**From:** [REDACTED]  
**Sent:** Wednesday, August 26, 2015 10:26 AM  
**To:** [REDACTED]  
**Subject:** A Study in the Treatment of Children and Adolescents With Major Depressive Disorder

Top whom it may concern,

While searching for the best evidence for therapy options in adolescents with depression I came across two articles that are almost exactly the same but with different page numbers. The papers cite two different clinical trials that have different NCT numbers but are the same trials. Is this a mistake? A bit concerning. Thank you. Amy

A double-blind efficacy and safety study of duloxetine fixed doses in children and adolescents with major depressive disorder.  
Emslie GJ, Prakash A, Zhang Q, Pangallo BA, Bangs ME, March JS.

J Child Adolesc Psychopharmacol. 2014 May;24(4):170-9. doi: 10.1089/cap.2013.0096. Epub 2014 May 9.

PMID:24815533

A double-blind efficacy and safety study of duloxetine flexible dosing in children and adolescents with major depressive disorder.

Atkinson SD, Prakash A, Zhang Q, Pangallo BA, Bangs ME, Emslie GJ, March JS.

J Child Adolesc Psychopharmacol. 2014 May;24(4):180-9. doi: 10.1089/cap.2013.0146. Epub 2014 May 9.

PMID: 24813026

A Study in the Treatment of Children and Adolescents With Major Depressive Disorder

<https://clinicaltrials.gov/ct2/show/NCT00849901>

A Study in the Treatment of Children and Adolescents With Major Depressive Disorder

<https://clinicaltrials.gov/ct2/show/NCT00849693>

