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Pediatric and Adult Placebo Response Rates in Placebo-controlled Clinical Trials Submitted to the US Food & Drug Administration 2012–2020

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Why is this article important to you?
The use of placebo concurrent control (placebo-controlled) is the most rigorous method of evaluating the safety and efficacy of investigational treatments. However, the use of a placebo group in pediatric product development can be challenging due to ethical considerations and potential differences in placebo response rates between adults and children. This study reports the US Food & Drug Administration's experience with placebo response rates in the pediatric population. Products studied under the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act between 2012 - 2020 were screened. Study characteristics including study type, primary efficacy endpoint(s), placebo response rates for the primary efficacy endpoint(s) and studied age range were collected. A total of 71 drug products used a placebo-controlled trial. Of these, 13 products had identical study design and trial characteristics including the primary efficacy endpoints between pediatric and adult studies. Fifteen products were studied in trials with identical study design but only different primary efficacy endpoints in pediatric and adult populations. Ten products had combined adolescent and adult trials with separate pediatric trials in younger age groups. In each of these cases, the pediatric placebo response was greater, for some trials, and less, for other trials, than the adult placebo response. Learners that complete this activity will be able to explain the difference between placebo response for adults and children.

ACPE Accreditation Statement
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UAN: 0665-0000-22-032-H03-P– ACPE 1 Contact Hours
Activity Type: Knowledge-based **Format:** Home-study **Target Audience**: 'P'

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The Accreditation Council for Continuing Medical Education designates this journal CE activity for 1 *AMA PRA Category 1™* credit. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Target Audience
Interprofessional team of Physicians, Pharmacists and PhDs.

Learning Objectives
After completing this activity, the learner will be able to:

1. Explain the difference of placebo response between pediatric and adult studies;

2. Discuss the possible reasons of difference of placebo response between pediatric and adult studies;

3. Provide examples of drug products with placebo-controlled trials in pediatric patients.

Requirements to Receive Credit
To receive continuing education credit, the learner must register for the educational activity, study the provided journal article and complete the online learning Post-event Self-assessment, as well as the online course Evaluation and CME/CPE Certificate. Credits and CME/CPE Certificates must be claimed within thirty (30) days of completing the article, Post-event Self-Assessment and Evaluation. Contact CE@ACCP1.org with any questions.

Disclosures:

Article Selection: Joseph S. Bertino Jr, PharmD, planner for this educational activity, has no relevant relationship(s) with ineligible companies to disclose.

Planners: Steve Crosby, MS, planner for this educational activity, has no relevant relationship(s) with ineligible companies to disclose.

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