COSMOS
Navigate the Compliance Universe

Report on Research Compliance Volume 19, Number 11. October 27, 2022
RRC E-Alerts: September 29, 2022

By Theresa Defino

FDA Publishes Draft Guidance on Including Children in Clinical Trials

Investigators wishing to study children should design trials "to maximize the amount of information gained and minimize the number of subjects involved" and consider the prospect of direct benefit as well as the scientific necessity of the research, according to draft guidance the Food and Drug Administration (FDA) issued Sept. 26. Open for comment for 90 days, the draft guidance seeks to encourage inclusion of children who have "historically" been excluded from trials "because of a misperception that [this] was in fact protecting them. This resulted in many FDA-approved, licensed, cleared or authorized drugs, biological products, and medical devices lacking pediatric-specific labeling information," FDA said in its announcement.

FDA explained that doctors are sometimes "left with no choice but to use a product that had not been reviewed by the FDA for safety and effectiveness in children" if that is "the best available treatment option for the child." The agency said it "became clear that children can be better protected by including them in clinical research." The draft guidance also offers details special considerations investigators should address, such as the use of placebo groups and sedation of research participants.

Link to announcement

Link to draft guidance