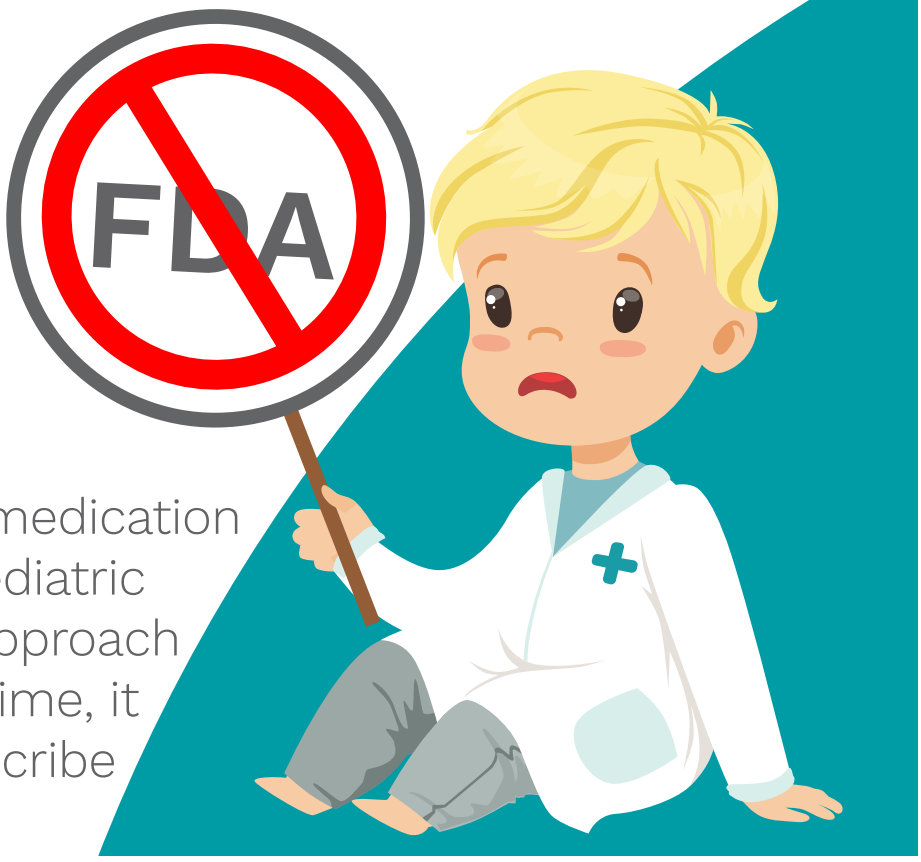
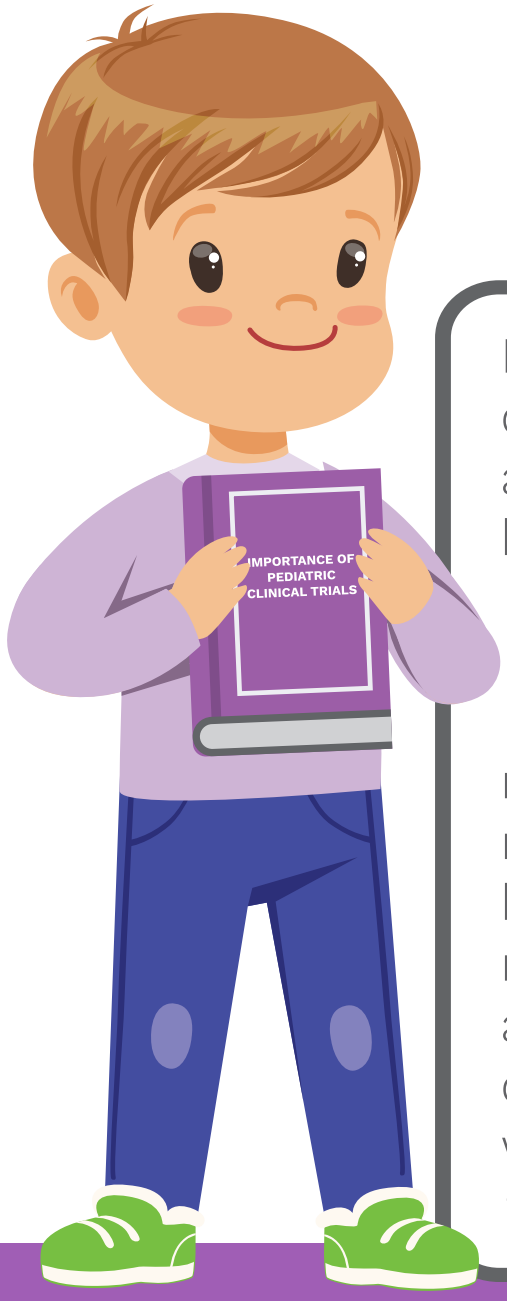
# **Understanding** the importance of pediatric clinical trials

## **Almost half** of all medications

prescribed to children are never actually tested in children during a clinical trial and are not approved by the Food and Drug Administration (FDA) for pediatric use. Instead, these medications are used “off label” and given at doses that are adjusted to the child’s weight with limited or no data demonstrating that the medication is effective or safe for pediatric patients. Although this approach works well most of the time, it isn’t an ideal way to prescribe medication to children.






Pediatric clinical trials not only provide doctors with better information about medication for children, but they also help researchers find medical breakthroughs that **greatly improve children's lives**.

Without clinical trials, life-saving medicine for preterm babies would not have been discovered, babies born to HIV positive mothers would not have the opportunity to grow up and lead healthy lives, and children diagnosed with acute leukemia would almost universally never live to attend prom or go to college.


**In recent** years,

pediatric medicine has been changing and the number of clinical trials that test these medications specifically in children and teens has increased.


Pediatric clinical trials for inflammatory bowel disease (IBD) allow researchers to determine what the **best dosage and frequency** of treatment is for children and teens. These trials allow the medical community to test the effects of these new treatments with the overall goal of providing safe and effective therapies specifically tailored for children with IBD.

# **No one can predict** how your child's body will respond to a medication.

This is because their response is based on how old your child is, where they are in their development, and which organ processes the medication. Children also have an increased ability to metabolize medicine, sometimes making higher doses of a medication necessary. That is why pediatric clinical trials are so **important** when it comes to helping the IBD community better understand what medications are ideal for children and which doses they should be given, from initial diagnosis, through their development, and on to adulthood.

# **Pediatric** clinical trials

allow researchers to understand several specific things about medications for children and teens, including the following:

- Is it **safe** to use in children?
- Is the medication **effective** in children?
- What is the **best** dose for their smaller bodies and more active metabolisms?

# **It is important** to remember...

... that it is only through patient participation in pediatric clinical trials that the FDA receives the data it needs to determine if new treatments for children and teens are safe and effective. Clinical trials also help researchers define better patient evaluation practices and allow them to determine the best way to use existing medications. By participating in pediatric clinical trials, your child not only gains access to a new treatment or medication, but they also help thousands of other pediatric patients gain access to more refined, FDA approved treatments and therapies.

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