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FDA partners with global agencies on development of COVID-19 therapeutics for children

by from the Food and Drug Administration's Office of Pediatric Therapeutics and Center for Drug Evaluation and Research, Division of Pediatric and Maternal Health

The importance of international collaboration in the development of drugs and biological products for children is especially evident in the global public health crisis resulting from COVID-19.

Worldwide partnerships help ensure that children's therapeutic needs are addressed without exposing pediatric patients to unnecessary or duplicative clinical trials. Collaboration among global regulators also facilitates the conduct of pediatric clinical trials that meet the optimum scientific rigor to support regulatory approval.

Participants in a recent webinar convened by the Institute for Advanced Clinical Trials (I-ACT) for Children encouraged development of COVID-19 therapeutics in children with the same urgency and quality as adults.

"We have a strong sense of shared responsibility across regulatory authorities to work together for pediatric COVID-19 therapeutics development," said Lynne Yao, M.D., FAAP, director of the Food and Drug Administration's (FDA's) Division of Pediatric and Maternal Health.

The webinar was co-moderated by Ed Connor, M.D., M.B.E., FAAP, founder and chair of I-ACT for Children, and Susan McCune, M.D., FAAP, director of the FDA's Office of Pediatric Therapeutics.

The Office of Pediatric Therapeutics facilitates monthly and ad hoc teleconferences to exchange information and views among global regulatory authorities, including the FDA, European Medicines Agency (EMA), Japan's Pharmaceuticals and Medical Devices Agency, Health Canada and Australia's Therapeutic Goods Administration. These teleconferences have been instrumental in providing a platform to discuss pediatric-related issues in the development of COVID-19 therapeutics for children.

As a result of this collaboration, the FDA and EMA released a Common Commentary (https://bit.ly/2VbbEvA) in June to streamline administrative processes and facilitate efficient submission of pediatric product development plans (i.e., initial Pediatric Study Plans and Paediatric Investigation Plans) for drugs and biological products to treat or prevent COVID-19.

Related Content

- I-ACT for Children virtual workshop Developing Pediatric Treatments for COVID-19
- Additional FDA Update columns