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Dated: July 28, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0771]

Advancing the Development of Pediatric Therapeutics Complex Innovative Trial Design; Public Workshop

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Advancing the Development of Pediatric Therapeutics (ADEPT 7) Complex Innovative Trial Design.'' The purpose of the public workshop is to discuss applications of complex and innovative trial designs in pediatric clinical trials.

DATES: The public workshop will be held virtually on September 1, 2021 (Day 1), from 10 a.m. to 3 p.m. Eastern Time and September 2, 2021 (Day 2), from 10 a.m. to 3 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration information.

ADDRESSES: The public workshop will be held in virtual format only. Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this public meeting via an online teleconferencing platform and will not be held at a specific location.

FOR FURTHER INFORMATION CONTACT: Evangela Covert, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5234, Silver Spring, MD 20993, 301–796–4075, *Evangela.Covert@fda.hhs.gov;* or Denise Pica-Branco, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6402, Silver Spring, MD 20993, 301–796–4075, *Denise.Picabranco@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Over the last two decades, great advances have been made in pediatric drug development. In addition, there is a growing recognition that complex and innovative trial designs have the potential to optimize drug development in small populations. Innovations that have been proposed include Bayesian and other methods of utilizing external historical information from previous pediatric trials or other populations (such as adults), adaptive designs, bridging biomarkers, etc. These designs tend to require more extensive discussion and collaboration between drug developers and regulators to implement effectively.

The Complex Innovative Trial Design Pilot Meeting Program (CID Program) facilitates and advances the use of these types of designs by providing for increased interactions between staff in the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research and sponsors accepted into the program. Several pediatric study designs have been accepted into the CID Program. This workshop is being organized in collaboration with the CID Program.

II. Topics for Discussion at the Public Workshop

The main objective of the ''Advancing the Development of Pediatric Therapeutics (ADEPT 7) Complex Innovative Trial Design'' workshop is to discuss opportunities for leveraging complex and innovative trial designs, understand the challenges with their applications, and develop solutions on how challenges in the designs can be overcome. The workshop will specifically focus on two topics of interest: Bridging biomarkers in pediatric extrapolation and Bayesian techniques in pediatric studies. In addition, the workshop will allow for an open dialogue around the use of these approaches among regulators, industry, academia, and patient organizations.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://go.umd.edu/ADEPT7*. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Early registration is recommended because space is limited; therefore, FDA may limit the number of participants from each organization.

If you need special accommodations due to a disability, please contact

Evangela Covert or Denise Pica-Branco (see **FOR FURTHER INFORMATION CONTACT**) no later than August 18, 2021, by 5 p.m. Eastern Time.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast at the following site: *https://collaboration.fda.gov/adept7*.

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm*. To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview*. FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Dated: August 2, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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