REAGAN-UDALL FOUNDATION
for the Food and Drug Administration

A Practical Research Agenda for Treatment Development for Stimulant Use Disorder

Virtual Public Workshop

Monday, October 18, 2021

12 – 5 p.m. ET

Event Description: The Reagan-Udall Foundation for the FDA, in collaboration with the U.S. Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), is hosting a virtual public workshop to discuss a practical research agenda toward treatment development for stimulant use disorder. Stimulant use disorder is defined in the DSM-5 as "the continued use of amphetamine-type substances, cocaine, or other stimulants leading to clinically significant impairment or distress, from mild to severe." Adverse outcomes related to stimulant use are a growing problem in the United States.[1,2] There are currently no effective pharmacological treatments for any type of stimulant use disorder. However, there are many opportunities to improve the study design of clinical trials for stimulant use disorder. Clinical trials that are more person-centered may result in increased sensitivity to detect a treatment effect, with the potential for such a treatment effect to be linked to more long-term outcomes that are meaningful both clinically and to the patient.[3] Meeting participants will respond to a proposed practical research agenda that focuses on innovation in clinical trial design and candidate endpoints for the evaluation of potential treatments for stimulant use disorder.

12 p.m. **Welcome**

- Susan Winckler, Reagan-Udall Foundation for the FDA

12:05 p.m. **Session 1: Efforts to Promote Treatment Development for Stimulant Use Disorder**

Presenters

- Janet Woodcock, U.S. Food and Drug Administration
- Nora Volkow, National Institute on Drug Abuse

12:45 p.m. **Session 2: Optimizing Clinical Trial Design for Stimulant Use Disorder**

Presenters

- David McCann, National Institute on Drug Abuse
- Madhukar Trivedi, UT Southwestern

[1] Jones CM, Compton WM, Mustaquim D. Patterns and Characteristics of Methamphetamine Use Among Adults — United States, 2015–2018. MMWR Morb Mortal Wkly Rep 2020;69:317–323. DOI: http://dx.doi.org/10.15585/mmwr.mm6912a1

[2] O'Donnell J, Gladden RM, Mattson CL, Hunter CT, Davis NL. *Vital Signs:* Characteristics of Drug Overdose Deaths Involving Opioids and Stimulants — 24 States and the District of Columbia, January–June 2019. MMWR Morb Mortal Wkly Rep 2020;69:1189–1197. DOI: http://dx.doi.org/10.15585/mmwr.mm6935a1external icon

[3] Kiluk BD, Carroll KM, Duhig A, et al. Measures of outcome for stimulant trials: ACTTION recommendations and research agenda. *Drug Alcohol Depend*. 2016;158:1-7. doi:10.1016/j.drugalcdep.2015.11.004

Panelists

- Sarah Akerman, Alkermes
- Maria Sullivan, Pear Therapeutics
- Jessica Hulsey, Addiction Policy Forum
- Frances Levin, Columbia University
- Robert Walsh, National Institute on Drug Abuse
- Maryam Afshar, U.S. Food and Drug Administration

Discussion

2:15 p.m. **Break**

2:30 p.m. **Session 3: Identifying Clinically Meaningful and Patient-Centric Endpoints**

Presenters

- Brian Kiluk, Yale School of Medicine

Panelists

- Michelle Peavy, University of Washington
- Philip Rutherford, Faces and Voices of Recovery
- Deborah Hasin, Columbia University
- Ivan Montoya, National Institute on Drug Abuse
- David Reasner, U.S. Food and Drug Administration
- Celia Winchell, U.S. Food and Drug Administration

Discussion

4 p.m. **Session 4: Future Directions for Stimulant Use Disorder Research**

Panelists

- Marta Sokolowska, U.S. Food and Drug Administration
- Nora Volkow, National Institute on Drug Abuse
- Brandee Izquierdo, SAFE Project
- Denise Leclair, Novartis
- F. Gerald Moeller, Virginia Commonwealth University
- Pamela Scott, U.S. Food and Drug Administration
- Nicole Caffiero, Cigna

Discussion

5 p.m. **Adjournment**

This activity is one part of a multi-part Foundation project related to substance use disorder. The multi-part project is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of an overall award of $173,835 of federal funds (100% of the project). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA, HHS, or the U.S. Government. For more information, please visit FDA.gov.