

PATIENT FOCUSED DRUG DEVELOPMENT MEETING FOR OPIOID USE DISORDER (OUD)



APRIL 17th, 2018; 10:00 am – 4:00 pm

AGENDA

- 9:00 – 10:00 am **Registration**
- 10:00 – 10:05 am **Welcome**
Sara Eggers, PhD
Office of Strategic Programs (OSP), Center for Drug Evaluation and Research (CDER), FDA
- 10:05 – 10:10 am **Opening Remarks**
Theresa Mullin, PhD
Associate Director for Strategic Initiatives, CDER, FDA
- 10:10 – 10:20 am **Background on Opioid Use Disorder and Treatment**
Maryam Afshar, MD
*Division of Anesthesia, Analgesia, and Addiction Products (DAAAP)
Office of New Drugs (OND), CDER, FDA*
- 10:20 – 10:25 am **The Road from PFDD Meetings to Clinical Trial Endpoints**
Elektra Papadopoulou, MD, MPH
Associate Director, Clinical Outcome Assessments Staff, OND, CDER, FDA
- 10:25 – 10:35 am **Overview of Discussion Format**
Sara Eggers, PhD
OSP, CDER, FDA
- 10:35 – 11:05 am **Panel #1 Discussion on Topic 1: Health Effects and Daily Impacts of OUD**
A panel of individuals and families will provide comments to start the discussion on significant health effects and daily impacts on opioid use disorder
- 11:05 – 12:00 pm **Large-Group Facilitated Discussion on Topic 1**
Individuals and families in the audience will be invited to add to the dialogue
- 12:00 – 1:00 pm **Lunch**
- 1:00 – 1:05 pm **Afternoon Welcome**
Sara Eggers, PhD
OSP, CDER, FDA
- 1:05 – 1:35 pm **Panel #2 Discussion on Topic 2: Current Approaches to Treatment of OUD**
A panel of individuals and families will provide comments to start the discussion on current approaches to treating opioid use disorder
- 1:35 – 2:20 pm **Large-Group Facilitated Discussion: Topic 2**
Individuals and families in the audience will be invited to add to the dialogue
- 2:20 – 2:45 pm **Break**
- 2:45 – 3:15 pm **Large-Group Facilitated Discussion: Topic 2 Continued**
- 3:15 – 3:45 pm **Open Public Comment**
- 3:45 – 4:00 pm **Closing Remarks**
Mitra Ahadpour, MD, DABAM
Deputy Director, Office of Translational Sciences (OTS) CDER, FDA

DISCUSSION QUESTIONS

Topic 1: Health effects and daily impacts of Opioid Use Disorder (OUD)

1. Of all the ways that OUD negatively affects your health and well-being, which effects have the most significant impact on your daily life? Examples of negative effects may include:
 - Effects of using opioids, such as confusion, constipation, or other symptoms;
 - Effects of opioid withdrawal, such as nausea, diarrhea, or other symptoms;
 - Effects of opioid “cravings;”
 - Impacts on ability to function in personal or professional life;
 - Emotional or social effects; and
 - Other potential effects.
2. How does OUD affect daily life on your best days? On your worst days?
3. How has your OUD changed over time?
4. What worries you most about your condition?

Topic 2: Current approaches to treatment of Opioid Use Disorder (OUD)

1. Are you currently using, or have you used in the past, any prescription medical treatments to treat your OUD? Such treatments may include buprenorphine, methadone, naltrexone, and others that your health care provider has prescribed. If so, please describe your experiences with these treatments.
 - How well have these treatments worked for you? How well have they helped address the effects of OUD that are most bothersome to you?
 - What are the biggest problems you have faced in using these treatments? Examples may include bothersome side effects, challenges getting the medicines, concern about stigma, and other possible problems.
2. Besides prescription medical treatments, are there other treatments or therapies that you currently use to address your OUD? If so, please describe. How well do these treatments or therapies help address the effects of OUD that are most bothersome to you?
3. Of all treatments, therapies, or other steps that you have taken to address your OUD, what have you found to be most effective in helping you manage your OUD?
4. What are the biggest factors that you take into account when making decisions about seeking out or using treatments for OUD?
5. What specific things would you look for in an ideal treatment for OUD?
6. If you had the opportunity to consider participating in a clinical trial studying experimental treatments for OUD, what factors would you consider when deciding whether or not to participate?

Docket Information: We encourage you to submit your written comments to the docket by June 18, 2018: <https://www.regulations.gov/document?D=FDA-2018-N-0987-0001> or go to www.regulations.gov and search for: **opioid use disorder patient-focused drug development**.