Advancing Psychedelic Clinical Study Design

Wednesday, January 31 from 10am to 2pm ET
Thursday, February 1 from 10am to 1pm ET
Virtual Public Meeting

Agenda

Meeting Description:
The Reagan-Udall Foundation for the FDA, in collaboration with the FDA, is hosting a virtual public workshop to bring together researchers, regulated industry, and other key stakeholders to discuss scientific issues that arise while working with psychedelics in clinical trials and drug development. In June 2023, FDA issued its first draft psychedelics guidance for industry, *Psychedelic Drugs: Considerations for Clinical Investigations*, to provide general considerations to sponsors developing psychedelic drugs for treatment of medical conditions (e.g., psychiatric disorders, substance use disorders). While the guidance highlights some of the challenges in designing clinical trials with psychedelics capable of yielding interpretable results, many questions remain about the most appropriate way to address these challenges. This workshop will explore empiric approaches to address key issues in psychedelic drug development and research.

Meeting Goals:

1. Understand the experiences of scientists working with psychedelics in FDA-authorized clinical studies and drug development
2. Explore considerations for psychedelic clinical trial designs
3. Explore perspectives and current research on set and settings in psychedelic clinical trials
4. Provide an overview of the June 2023 draft FDA guidance for industry: *Psychedelic Drugs: Considerations for Clinical Investigations*

Day 1 (1/31/2024)

10 am — Welcome

Speaker:

- Susan C. Winckler, RPh, Esq, Reagan-Udall Foundation for the FDA

10:05 am — Opening Remarks

Speaker:

- Patrizia Cavazzoni, MD, U.S. Food and Drug Administration

10:15 am — Session 1: Overview of FDA's Psychedelics Clinical Investigation Guidance

This session will provide a brief overview of the June 2023 draft FDA guidance for industry: *Psychedelic Drugs: Considerations for Clinical Investigations*

Speaker:

- Tiffany Farchione, MD, U.S. Food and Drug Administration

10:40 am **Session 2: Psychedelics Study Design, Control Conditions, and Blinding**

This session will focus on challenges in selecting control conditions to create blinding for psychedelic studies, to reduce bias and to determine whether changes in outcome measures can be attributed to the psychedelic.

Speakers:

- Suresh Muthukumaraswamy, PhD, University of Auckland
- Franz Vollenweider, MD, University of Zürich

Respondents:

- Matt Butler, MD, King's College London
- Michael Davis, MD, PhD, Usona Institute
- Bernard Fischer, MD, U.S. Food and Drug Administration

11:40 am **Break**

11:50 am **Session 3: Dosing**

This session will focus on issues related to psychedelic drug dosing (dose-response, single vs. repeat dosing, microdosing, etc.) in three substance areas: MDMA, Psilocybin, and LSD.

Speakers:

- Robert Barrow, MSc, MindMed
- Guy Goodwin, DPhil, Compass Pathways
- Berra Yazar-Klosinski, PhD, Lykos Therapeutics

Respondents:

- Peter Hendricks, PhD, University of Alabama at Birmingham
- Jennifer Mitchell, PhD, University of California, San Francisco
- Martine Solages, MD, U.S. Food and Drug Administration

1 pm **Session 4: Durability of Treatment Response**

This session will focus on the durability of the psychedelic therapeutic response and discuss the conditions under which additional treatment should be considered.

Speakers:

- Michael P. Bogenschutz, MD, NYU Langone Center for Psychedelic Medicine
- Carla Canuso, MD, Johnson & Johnson Innovative Medicine

Respondents:

- Valentina Mantua, MD, PhD, U.S. Food and Drug Administration
- Charles L. Raison, MD, University of Wisconsin-Madison

2 pm **Adjourn Day 1**

Day 2 (2/1/2024)

10 am **Welcome**

Speaker:
Susan C. Winckler

10:10 am **Session 5: Set and Setting**

This session will focus on set (the mindset of the participant prior to and after the psychedelic session, the role of psychotherapy) and setting (the way the session room is designed, activities during the psychedelic session).

Speakers:

- Ido Hartogsohn, PhD, Bar-Ilan University
- David Yaden, PhD, Johns Hopkins University

Respondents:

- Brian Anderson, MD, University of California, San Francisco
- Javier Muniz, MD, U.S. Food and Drug Administration

11:20 am **Session 6: Overview of FDA Regulatory Authority**

This session will provide an overview of the limits of FDA authorities after a new drug application for any drug product is approved.

Presenter

- Tiffany Farchione

11:40 am **Session 7: Considerations for Potential Psychedelic Use in the Real World**

This session will include a discussion focused on understanding current use and considerations for potential future use of psychedelics.

Speakers:

- Richard C. Dart, MD, PhD, Denver Health and Hospital Authority
- Mason Marks, MD, JD, Harvard Law School
- Mark H. Rapaport, MD, University of Utah School of Medicine
- Lisa Robin, MLA, Federation of State Medical Boards
- Marta Sokolowska, PhD, U.S. Food and Drug Administration
- Ilse Wiechers, MD, MPP, MHS, U.S. Department of Veterans Affairs

12:55 pm **Closing Remarks**

Susan C. Winckler

1 pm **Adjourn Day 2**

Funding Disclosure: 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 $1,720,109 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.