National Institutes of Health Workshop: "Psychedelics as Therapeutics; Gaps, Challenges & Opportunities." January 12-13, 2022. (All times are Eastern Standard Time)

Agenda and Speaker Titles

Day 1

9:00 AM Joshua Gordon (NIMH) Directors Welcome and Opening remarks.

9:30-10:15 **Franz Vollenweider** (University of Zurich): *Neurobiology of psychedelic drug effects on self-processing, affect, and social cognition: implications for potential therapeutic change.*

Theme 1: Basic and Translational Research

10:15 Introduction to basic and translational research theme.

10:20 **Gabriella Gobbi** (McGill University): *Psychedelics for mental health: translating preclinical data into clinical practice.*

10:40 Bryan Roth (University North Carolina): The promises and perils of psychedelic pharmacology.

Break 11:00 to 11:15

- 11:15 **Clint Canal** (Mercer University): How informative are preclinical models of psychedelic drug mechanisms? From 5-HT2A to another place far away.
- 11:35 **Scott Thompson** (University of Maryland): *Optimizing psychedelics for treating neuropsychiatric disease: the preclinical perspective.*
- 11:55 **Gitte Knudsen** (University of Copenhagen): 5-HT2AR PET imaging and functional connectivity as biomarkers of target engagement.

12:15-1:00 **PANEL**

Franz, Gabriella, Bryan, Clint, Scott, Gitte. Rob Malenka (Stanford University) as discussant (10 min)

1:00 PM Closeout

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Day 2

Theme 2: Clinical Trials

- 9:30 AM Introduction to clinical trials theme.
- 9:35 **Michael Mithoefer** (Medical University South Carolina): *MDMA trial design, what have we learned?*
- 9:55 **Michael Bogenschutz** (New York University): *Does subjective experience mediate the putative therapeutic effects of psychedelics?*
- 10:15 **Jennifer Mitchell** (University of California San Francisco): *Safety and efficacy of MDMA for the treatment of PTSD.*
- 10:35 Matthew Johnson (Johns Hopkins University): Psilocybin and smoking cessation.
- 10:55 **Celia Morgan** (University of Exeter): *Ketamine assisted psychotherapy in the treatment of alcohol use disorder and other addictions.*

11:15-12:00 **PANEL**

Michael M, Michael B, Jennifer, Matthew, Celia. **Elias Dakwar** (Columbia University) as discussant (10 min)

12:00-12:30 Lunch

<u>Theme 3:</u> <u>Optimizing Future Clinical Trial Designs</u>

- 12:30 PM Introduction to optimizing future clinical trial designs.
- 12:35 **Ido Hartogsohn,** (Bar-Ilan University): *Set and Settings in psychedelic clinical trials and moving forward.*
- 12:55 **Suresh Muthukumaraswamy** (University of Auckland): *Overcoming confounds in psychedelic clinical trials: designs and measurement.*
- 1:15 **Paul Appelbaum** (Columbia University): *Ethical considerations in conducting psychedelic research.*
- 1:40 **Javier Muniz** (FDA): Considerations of study design and interaction of medication and medical practice in drug registration trials.

2:10-2:55 **PANEL**

Ido, Suresh, Paul, Javier, **Susan Learned** (Independent Pharmaceutical Consultant) as discussant (10 min)

2:55 PM Nora Volkow (NIDA): Directors summation and Closing remarks