

How to Conduct Trials that Enroll Suicidal Patients

Chairs:

Jill Harkavy-Friedman, PhD Samuel T. Wilkinson, MD

Disclosures

Jill Harkavy-Friedman

SVP of Research at the American Foundation for Suicide Prevention

Associate Professor of Clinical Psychology, in Psychiatry Columbia University (unpaid)

No paid consultations to other organizations

Sam Wilkinson

Yale School of Medicine

Dr. Wilkinson has received funding from the following sources:

- Federal Government: NIH and AHRQ
- Non-profit agencies: the Patient-Centered Outcomes Research Institute (PCORI), Brain and Behavior Research Foundation (formerly NARSAD), Robert E. Leet and Clara Guthrie Patterson Trust, American Foundation for Suicide Prevention (AFSP)
- Pharmaceutical: Janssen, Sage, Oui Therapeutics, administered through Yale University for conduct of clinical trials
- Department of Psychiatry, Yale School of Medicine

Dr. Wilkinson has received consulting fees from Janssen, Sage, Oui Therapeutics, LivaNova, and Eleusis in the last 3 years

Yale has an Institutional Conflict of Interest (Esketamine)



Speakers

Larry Alphs, MD, PhD
Michael Bloch, MD, MS
DJ Fu, MD, PhD
Gerard Sanacora, MD, PhD
Zimri Yaseen, MD
Jill Harkavy-Friedman, PhD
Sam Wilkinson, MD

Speakers



Larry Alphs, MD



Dong-Jing (DJ) Fu, MD



Michael Bloch, MD, MHS Gerard Sanacora, MD, PhD



Zimri Yaseen, MD



Most trials have systematically excluded patients at risk of suicide. Why?

- Regulatory challenges
- -Research is too risky for those at elevated risk of suicide
- -Discomfort working directly with high-risk patients

Key Challenges Conducting Trials

- -Choosing the proper comparator
- -Balancing ethical principles with scientific aims
- -Timely management of risk when collecting self-report information