Reduction in World Health Organization (WHO) Drinking Risk Level as a Primary Endpoint for Alcohol Treatment Trials

A Review of Initiatives by the FDA, NIH, and the Alcohol Clinical Trials Initiative (ACTIVE)

Chair:

Stephanie O'Malley, PhD

Disclosure

- Member of ASCP ACTIVE work group supported by Alkermes, Amygdala, Arbor Pharma, Ethypharm, Indivior, Lundbeck, Otsuka;
- Donated study medications: AstraZeneca, Novartis
- Consultant/advisory board member – Alkermes, Amygdala, Indivior, Mitsubishi Tanabe, Opiant

Alcohol Clinical Trials Initiative (ACTIVE) Workgroup - CURRENT

Pharmaceutical Companies:
Alkermes
Amygdala
Arbor Pharm
Ethypharm
Indivior
Lundbeck
Otsuka

NIAAA :
Raye Litten
Dan Falk
Joanne Fertig
Megan Ryan

NIDA :
David McCann
Tanya Ramey

Academic Experts:
Ray Anton – Chair
Henri-Jean Aubin (Europe)
Debbie Hasin
Hank Kranzler
Chuck O'Brien
Stephanie O'Malley
Karl Mann (Europe)
Roger Meyer
Katie Witkiewitz

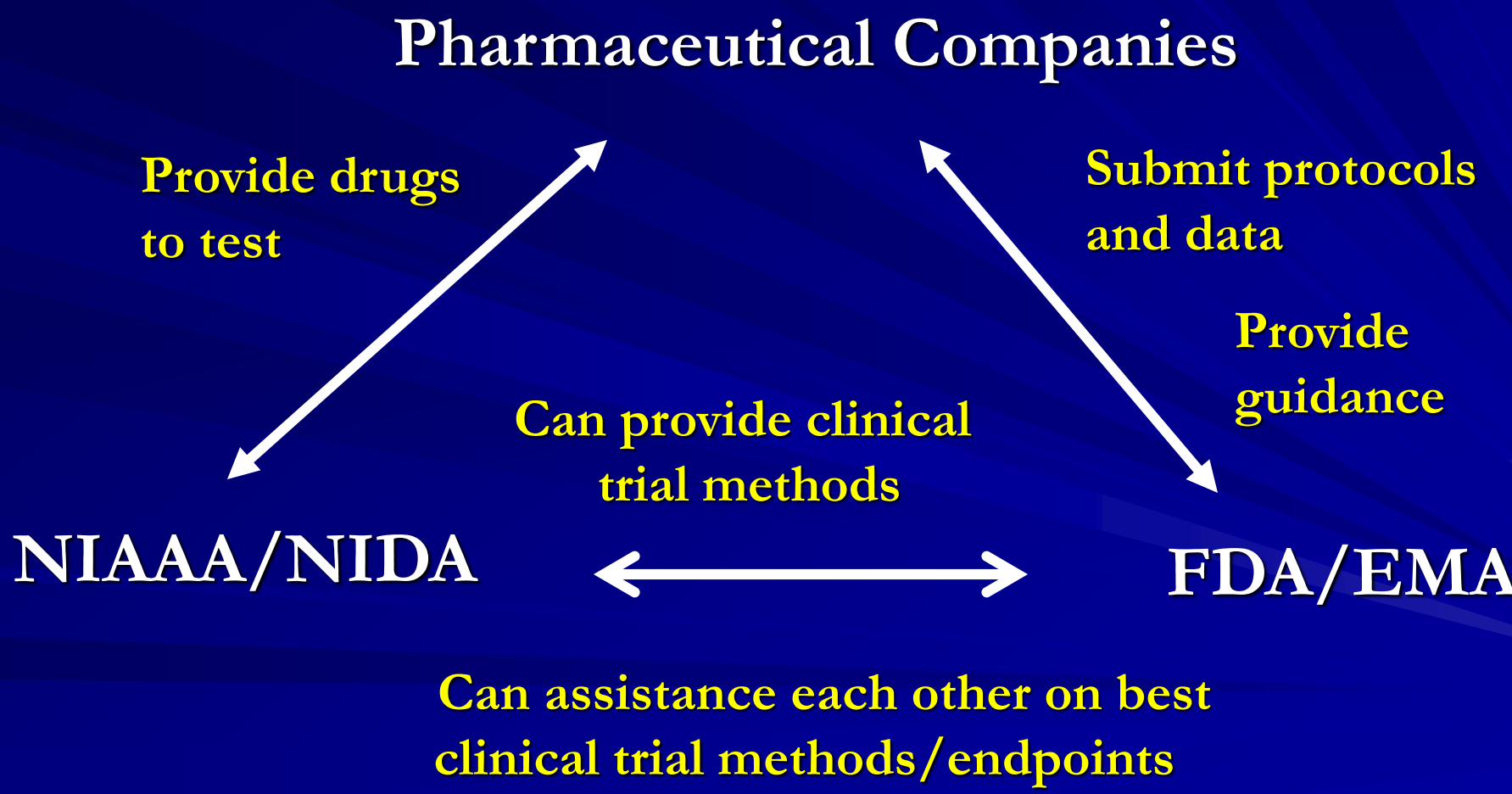
EMA:
Michael Buhlen

FDA:
Celia Winchell
Tom Permutt

Insurance Industry:
Keith Isenberg

Steering Committee: Anton, Falk, Litten, Kranzler, O'Malley, Silverman (Alkermes), Winchell, Snyder (Parthenon Group -ASCP)

Triangle of Opportunities



Mission of ACTIVE

To develop a consensus on best methods for clinical trials and to improve “regulatory guidance” for approval of medications to treat alcohol use disorders.

Dissemination

- **Publications**
- **Presentations**
- **Meeting Minutes**

https://www.ascpp.org/resources



Consensus Issues being Addressed for Alcohol Dependence Clinical Trials

- Handling missing data
- Placebo response
- Primary drinking outcome/endpoint measures
- Clinical trial length
- Inclusion of psychiatric co-morbidities?
- Need for patient reported outcome (PRO) scales
- PRO and/or biomarkers of drinking as endpoints

Speakers

- Deborah Hasin, PhD, Columbia University

  Change in WHO drinking risk levels and clinical outcomes: Findings from the US general population

- Katie Witkeiwitz, PhD, University of New Mexico

  The relationship of World Health Organization drinking risk levels to how patients “feel and function” in an alcohol clinical trial.

Speakers

- Daniel Falk, PhD

  Measuring response to alcohol pharmacotherapy: Efficacy endpoints based on reductions in the World Health Organization risk levels of alcohol consumption.

- Bernard Silverman, MD, Alkermes

  Discussant