ACTIVE Workgroup Meeting Minutes

March 18 – 19, 2025
Sheraton Rockville
920 King Farm Blvd. | Rockville, MD 20850
Meeting Room: King Farm AB

Participants:

Ray Anton, presiding
Maryam Afshar, day two
Henri-Jean Aubin, virtual
Bartholt Bloomfield-Clagett, day two
Michaela Hoffman
Zachary Illg, day two
Karl Mann
Stephanie O'Malley
Valentine Pascale
Ismene Petrakis, guest
Lara Ray
Joseph Schacht
Bernard Silverman
Maria Sullivan
Garth Whiteside
Katie Witkiewitz
Conrad Wong
Constance Zou, day two
Laura Reynolds, staff

Minutes:

1. ***Welcome:*** R. Anton welcomed the group, provided an overview of the program, as well as provided an exciting update on the WHO-RDL measure.
    a. ***Introductions:*** ACTIVE guests and members introduced themselves, sharing their backgrounds and involvement with the organization. R. Anton emphasized the value of having experts from diverse fields, such as psychology, psychiatry, and neuroscience, pharmaceutical development and regulatory bodies sharing ideas and data.
    b. ***Program Overview:*** Day one will include presentations focusing on issues of new medications and how they might overlap with other medical or psychiatric disorders. Day two will consist of updates on the on two long-term projects that ACTIVE has been working on: 1.) the WHO-RDL measure and 2.) how early stage "clinical laboratory paradigms or protocols" might inform medication effectiveness estimates for clinical stage regulatory trials
    c. ***Project Updates:*** R. Anton shared the background of ACTIVE's WHO-RDL project which the group has been working on for the last 5-7 years and noted that it was recently approved. Additionally, he discussed the plans for two papers, with the target of potentially being published in JAMA.

2. ***Potential Role for Incretins in the Treatment of Alcohol Use Disorder:*** M. Sullivan presented on the potential role of incretins in the treatment of AUD. The discussion focused on the potential use of incretin therapies, particularly GLP-1 receptor agonists like semaglutide, for treating Alcohol Use Disorder (AUD). She highlighted the high prevalence of AUD, the low treatment rates, and the limitations of current therapies. The mechanism of action of GLP-1 in the brain's reward pathway was explained, and she presented evidence from non-clinical studies and real-world data suggesting that incretin therapies may reduce alcohol consumption and craving. A recent phase 2 clinical trial showed that low-dose semaglutide reduced alcohol self-administration and craving in non-treatment-seeking individuals with AUD. M. Sullivan concluded by summarizing the ongoing clinical

development of incretin therapies for AUD and their potential advantages over existing treatments.

3. ***Group Discussion:*** The group discusses recent evidence and potential for a novel mechanism to address alcohol use disorder. They explore sex differences in prevalence and trial enrollment, as well as concerns about functional unblinding due to weight loss effects. The discussion touches on trial design considerations, including participant BMI, dosing, and length of trials. They also consider the impact of weight loss on alcohol consumption measurements and the potential to examine calorie sources. The conversation concludes with interest in imaging studies to validate the mechanism's effects on dopamine activation in response to alcohol cues.

4. ***Development of a Selective Nociceptin/Orphanin FQ Receptor Partial Agonist for Alcohol Use Disorder – Lessons Learned and Path Forward:*** G. Whiteside presented on Imbrium Therapeutics' development of a selective Nociceptin/Orphanin FQ receptor (NOP) partial agonist for alcohol use of disorder. He began by discussing the development strategy and progress of Sunobinop, a drug aimed at several indications including to treat alcohol use disorder. The unique mechanism of Sunobinop was highlighted stating that it targets NOP receptors that have a distinct pharmacology from the traditional mu opioid receptor and without some of the liabilities. The drug has shown potential in treating insomnia associated with alcohol use disorder and has a unique sleep-inducing effect. G. Whiteside also discussed the safety profile of Sunobinop, which showed the drug was well tolerated across all populations studied to date. The drug was found to be effective in reducing the number of awakenings and improving sleep quality in patients with alcohol use disorder who were in recovery. It was also mentioned the ongoing Phase 2 study in patients who are currently drinking. The conversation ended with a discussion on the challenges of determining the appropriate duration of dosing and the potential impact of concomitant medications on assessing the drug's effectiveness. It was an interactive presentation with a great deal of group discussion and feedback. The below suggestions were provided by the group:

    a. **Group Feedback:**

        i. Consider conducting further correlation analysis on biomarker data from the 8-week trial with 40-50 patients per group to understand the correlation between biomarkers and treatment outcomes.
        ii. Implement post-trial monitoring protocol for patients who relapse while on active medication.
        iii. Consider studying the pharmacodynamic interactions between the drug and alcohol when dosing at night with higher quantities of alcohol for experienced heavy drinkers.
        iv. Simplify the sleep diary for future trials to reduce data variability and noise.
        v. Design and implement a brief behavioral intervention as a control platform for future trials.
        vi. Monitor and document cannabis use effects on trial outcomes as part of the ongoing study.
        vii. Analyze the relationship between sleep improvement and alcohol consumption reduction in current trial data.

viii. Consider potential applications for patients transitioning from benzodiazepines.
ix. Consider stratifying future study randomization by whether people are abstaining at initiation of treatment or not.
x. Document and analyze withdrawal symptoms in current study participants for potential signals related to sleep effects.
xi. Investigate the relationship between nicotine status and treatment response in current study data.
xii. Track and analyze motivation levels of participants in relation to treatment outcomes.
xiii. Consider studing the glutamate system interactions in participants with comorbid conditions.
xiv. Consider expanding data collection and reporting on euphoria effects in future alcohol use disorder studies.
xv. Put more emphasis on ISI vs PSQI as a more common and appropriate tool for use in AUD population.

ACTION ITEM:

a. Future meeting agenda topic regarding THC usage/ trial design and how is it managed – should be a stratification variable?

5. ***Alcohol Use Disorder and Related Comorbid Disorders - Opportunities and Challenges in*** *Designing Clinical Trials:* I. Petrakis discussed the importance of considering both alcohol use disorder and related comorbid disorders when designing clinical trials, particularly alcohol use disorder (AUD) and post-traumatic stress disorder (PTSD). She emphasized the high prevalence and clinical relevance of comorbidity, noting that 37% of those with substance use disorders also have mental illness. I. Petrakis noted the challenges in designing studies for comorbid conditions, including identifying target populations, setting inclusion and exclusion criteria, and selecting appropriate outcomes. To illustrate the challenges, she discussed a proof-of-concept study she and her team conducted using a combination of naltrexone and buprenorphine to treat AUD and PTSD, highlighting the complexities of studying dual disorders and the need for more inclusive research approaches. She concluded by stating that there are exciting opportunities to design studies in comorbid conditions because of the interesting neurobiology as well as the clinical need. Additionally, she noted the complicated challenges in the study design included identifying targets, as well as balancing "real world" with scientific purity. Following her presentation, the full group explored the challenges in designing clinical trials for comorbid disorders, including recruitment difficulties, defining appropriate populations, and getting pharmaceutical industry support. The discussion touched on using big databases, comparative effectiveness trials, and more targeted approaches based on biological mechanisms. They also consider how motivation levels and social factors may impact treatment outcomes.

6. ***Review of Issues Raised During FDA Approval of the WHO-RDL Metric and Next Steps For Evaluating Alcohol Use Disorder Clinical Trial Length***: K. Witkiewitz presented a review of the issues raised during the FDA approval of the WHO Risk Drinking metric for evaluating medication efficacy. She discussed the timeline, the correlation between post endpoint and clinical outcomes, and the potential for other fit for purpose measurements. She also highlighted the importance of patient and provider perspectives in the development of new endpoints. She then presented some preliminary analyses on the durability of the WHO

endpoint and the effect of trial duration on effect sizes. The team discussed potential next steps, including conducting a meta-regression. The presentation ended with a discussion on the potential for communication with the EMA regarding the qualification of the new endpoint.

ACTION ITEMS:

a. Follow-up with researchers in Dr. Lara Ray's lab to complete the meta-regression on trial length as a new ACTIVE paper.
b. Dr. Mann to contact the EMA to inform them of the FDA decision and ask if they wanted to review the work the FDA had done to come to that decision.
c. M. Afshar will identify and provide information about the mechanism/name of how EMA and FDA communicate with each other

7. ***Alcohol Use Disorder RCT Length as A Function of Baseline Drinking/ Population Characteristics. Initial Analyses of Drinking Over Time and Medication Effect Sizes***: M. Hoffman discussed a project involving the combination of five studies on alcohol use and abuse. The studies were conducted in a similar manner and had overlapping variables. She discussed the differences in study length and the average count of missing days across the studies. The discussion also touched on the study completers, baseline characteristics, and substance use variables. M. Hoffman raised questions about the best way to align the data from different studies for a large simulation and comparison purposes. The conversation ended with a discussion on the utility of the program and the need for further analysis on the effect sizes and sample size calculations with emphasis on site differences and other salient variables

ACTION ITEMS:

a. C. Wong will bullet point out his suggestions and share with M. Hoffman and R. Anton.
b. Study the relationship between trial duration and safety/efficacy outcomes to determine optimal trial length

8. ***Human Laboratory Endpoints for Early Efficacy Testing to De-risk Alcohol Use Disorder Medication***: L. Ray discussed the potential of clinical laboratories or proof of concept protocols in determining the efficacy of medications. She highlighted the importance of understanding the correlation between laboratory and clinical outcomes to effectively develop medications. Additionally, she presented a study that demonstrated the association between the signal detection in the clinical laboratory and the gold standard, Randomized Clinical Trials. The study focused on subjective response to alcohol and alcohol cue reactivity. L. Ray emphasized the need for more prescriptive and informed methods in conducting this work. The presentation concluded with a discussion on the potential of enrolling treatment-seeking individuals in clinical trials to get a bigger signal for dose-finding studies.

ACTION ITEM:

a. Continue collecting and analyzing data from clinical trials to update the meta-regression database with new studies

9. ***A Clinical Laboratory Alcohol Self-Administration Paradigm for Assessing the Effects of Medications for Alcohol Use Disorder:*** J. Schacht discussed the development and use of an alcohol free choice self-administration paradigm for testing medication effects on alcohol consumption in non-treatment seeking individuals with alcohol use disorder (AUD). The model involves administering a priming drink followed by the opportunity to self-administer (buy) additional drinks over a 2 hour period in a controlled lab setting. Key outcomes include subjective responses to alcohol and number of drinks consumed. He highlighted that this paradigm allows for testing medication effects in people not actively trying to reduce drinking, which can provide insight into a drug's potential biological/pharmacological efficacy. J. Schacht noted some limitations of the model, including variability in oral alcohol absorption and the need to carefully consider the relative value of the alternative reinforcer (money). The paradigm has been validated with naltrexone, showing reduced stimulation and drinking in AUD participants compared to placebo. Following the introduction of the paradigm, he discussed several studies on medications for alcohol use disorder (AUD) and presented data on naltrexone, gabapentin, aripiprazole, and tolcapone. The studies examined how genetic factors and personality traits like impulsivity influence medication effectiveness. Key findings include aripiprazole being more effective in people with high impulsivity or genetic predisposition to high dopamine tone, while tolcapone reduced drinking specifically in those with a certain genetic variant affecting dopamine metabolism. The importance of identifying subgroups who may respond better to different medications was emphasized, as these drugs are not likely to be effective for all AUD patients.

ACTION ITEMS:

a. Develop more prescriptive guidelines for human laboratory models in alcohol use disorder studies
b. Investigate dose-finding studies using human laboratory models for novel mechanisms of action
c. FDA Team: Provide guidance on specific areas where ACTIVE can help facilitate questions that they might have about the relationship of clinical laboratory studies and clinical trial guidance.

10. ***Closing:*** The meeting concluded with group discussion focusing on the differences between alcohol oral administration and systemic (IV) administration, with a discussion on the advantages of intravenous administration for studying physiological effects. The group also discussed the use of a hybrid model for studying alcohol consumption, which combines elements of a laboratory setting with naturalistic drinking behavior. The meeting also touched on the importance of genetics in drug development and the potential for repurposing drugs for alcohol treatment. The group also discussed the challenges of conducting clinical trials and the need for more comprehensive studies. The conversation ended with a discussion on the potential for public-private partnerships in drug development and the need for better communication between academic settings and pharmaceutical companies. Additionally, continued discussion is needed on the following items:

ACTION ITEMS:

a. Consider developing consensus guidelines/best practices for experimental medicine studies and clinical laboratory protocols to make them more standardized and appealing to pharmaceutical companies

b. Explore opportunities to continue working with FDA on identifying additional clinically meaningful endpoints beyond WHO endpoints
c. Plan the next virtual meeting for November
d. Consider alternative venues for future in-person meetings that are convenient for FDA representatives
e. R. Anton wants to keep the conversation going with phase II trials.
f. (C. Wong question) WHO Endpoint – could there be continued momentum identifying clinically relevant endpoints that could help inform the effectiveness of a novel drug in clinical trials?
    i. ACTIVE core workgroup to discuss this
    ii. Does it impact the length of the trial matter or vary across medications?
    iii. How can alcohol and other biomarkers be incorporated into clinical trial efficacy results? Are they additive to verbally reported drinking?

ACTIVE Publications

(Published/In-Press/Submitted Papers)

- Richards Dylan K, Tuchman Felicia R, Hallgren Kevin A, Kranzler Henry R, Aubin Henri-Jean, O'Malley Stephanie S, Mann Karl, Aldridge Arnie, Anton Raymond F, Witkiewitz Katie (2024). Reductions in World Health Organization Risk Drinking Level are Associated with Reductions in Alcohol Use Disorder Diagnosis and Criteria: Evidence from an Alcohol Pharmacotherapy Trial. Journal of Addiction Medicine, 18(4), 418-424.
- Tuchman, F.R., Hallgren, K.A., Richards, D.K., Aldridge, A., Anton, R.F., Aubin, H.-J. et al. (2024) Reductions in WHO risk drinking levels correlate with alcohol craving among individuals with alcohol use disorder. Alcohol: Clinical and Experimental Research, 48, 420–429. Available from: https://doi.org/10.1111/acer.15257
- Aldridge AP, Zarkin GA, Dowd WN, Witkiewitz K, Hasin DS, O'Malley SS, Isenberg K, Anton RF. The Relationship Between Reductions in WHO Risk Drinking Levels During Treatment and Subsequent Healthcare Costs for the ACTIVE Workgroup. J Addict Med. 2021 Dec 3. doi: 10.1097/ADM.0000000000000925. Epub ahead of print. PMID: 34864785.
- Witkiewitz K, Kranzler H, Hallgren K, Hasin D, Aldridge A, Zarkin G, Mann K, O'Malley S, and Anton RF. Stability of Drinking Reductions and Long-term Functioning Among Patients with Alcohol Use Disorder. Journal of General Internal Medicine. 2021 Feb; 36(2):404-412. PubMed PMID: 33180306; PubMed Central PMCID: PMC7878601.
- Shmulewitz D, Aharonovich E,Witkiewitz K, Raymond RF, Kranzler HR, Scodes J, Mann KF, Wall MM, Hasin D. The World Health Organization Risk Drinking Levels Measure of Alcohol Consumption: Prevalence and Health Correlates in US Adult Nationally Representative Surveys, 2001-2002 and 2012- 2013. American Journal of Psychiatry. 2021 Jan 21. PubMed PMID: 33472388.
- Witkiewitz K, Heather N, Falk DE, Litten RZ, Hasin DS, Kranzler HR, Mann KF, O'Malley SS, Anton RF. World Health Organization risk drinking level reductions are associated with improved functioning and are sustained among patients with mild, moderate and severe alcohol dependence in clinical trials in the United States and

United Kingdom. Addiction. 2020 Sep;115(9):1668-1680. doi: 10.1111/add.15011. Epub 2020 Mar 10. PMID: 32056311; PMCID: PMC7841874.

- Knox J, Scodes J, Witkiewitz K, Kranzler H, Mann K, O'Malley S, Wall M, Anton R, Hasin D, ACTIVE Group. Reduction in World Health Organization (WHO) Risk Drinking Levels and Cardiovascular Disease. Alcohol Clinical and Experimental Research. 2020 Aug; 44(8):1625-1635. PubMed PMID: 32619058; PubMed Central PMCID: PMC7484295.
- Anton RF, Witkiewitz K, Falk D, Litten R, Hasin D, Mann K, O'Malley SS., Response to Dr. Mark Litt Commentary. Alcohol Clinical and Experimental Research. 2019 Aug 5. PubMed PMID: 31381170.
- Witkiewitz K, Falk DE, Litten RZ, Hasin DS, Kranzler HR, Mann KF, O'Malley SS, Anton RF. Maintenance of World Health Organization Risk Drinking Level Reductions and Posttreatment Functioning Following a Large Alcohol Use Disorder Clinical Trial. Alcoholism: Clinical and Experimental Research. 2019 May; 43(5): 979-987. PubMed PMID: 30951210; PubMed Central PMCID: PMC6502682.
- Knox J, Wall M, Witkiewitz K, Kranzler HR, Falk DE, Litten R, Mann K, O'Malley SS, Scodes J, Anton R, Hasin DS. Reduction in Non-abstinent World Health Organization (WHO) Drinking risk Levels and Drug Use Disorders: 3-year Follow-up Results in the US General Population. Drug Alcohol Depend. 2019 Apr 1; 197: 228-235. PubMed PMID: 30852375; PubMed Central PMCID: PMC440807.
- Falk DE, O'Malley SS, Witkiewitz K, Anton RF, Litten RZ, Slater M, Kranzler HR, Mann KF, Hasin DF, Johnson B, Meulien D, Ryan M, & Fertig J. Evaluation of Drinking Risk Levels as Outcomes in Alcohol Pharmacotherapy Trials: A Secondary Analysis of 3 Randomized Clinical Trials. JAMA Psychiatry. 2019 March 13. PubMed PMID: 308652321; PubMed PMCID: PMC6450273.
- Knox J, Scodes J, Wall M, Witkiewitz K, Kranzler HR, Falk DE, Litten RZ, Mann KF, O'Malley SS, Anton RF, Hasin DS; Alcohol Clinical Trials (ACTIVE) Workgroup. Reduction in non-abstinent WHO drinking risk levels and depression/anxiety disorders: 3-year follow-up results in the US general population. Drug Alcohol Depend. 2019 Feb 14; 197:228-235. PubMed PMID: 30852375.
- Witkiewitz K, Kranzler HR, Hallgren KA, Hasin DE, Mann KF, Falk DE, Litten RZ, O'Malley SS, & Anton RF. Drinking Risk Level Reductions Associated with Improvements in Physical Health and Quality of Life Among Individuals with Alcohol Use Disorder. Alcoholism: Clinical and Experimental Research. 2018 Dec; 42(12):2453-2465. PubMed PMID: 30395350; PubMed Central PMCID: PMC6286196.
- Knox J, Wall M, Witkiewitz K, Kranzler HR, Falk DE, Litten RZ, Mann KF, O'Malley SS, Scodes J, Anton RF, & Hasin DS. Reduction in Non-Abstinent WHO Drinking Risk Levels and Change in Risk for Liver Disease and Positive AUDIT-C Scores: Prospective 3-Year Follow-Up Results in the US General Population. Alcoholism: Clinical and Experimental Research. 2018 Nov; 42(11)2256-2265.
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- Mann K, Aubin HJ, & Witkiewitz K. Reduced Drinking in Alcohol Dependence Treatment, What is the Evidence? European Addiction Research. 2017 Sep 22;23(5):219-230. PubMed PMID: 28934736.

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- Witkiewitz K, Wilson AD, Pearson MR, Hallgren KA, Falk DE, Litten RZ, Kranzler HR, Mann KR, Hasin DS, O'Malley SS, & Anton RF. Temporal Stability of Heavy Drinking Days and Drinking Reductions Among Heavy Drinkers in the COMBINE Study. Alcoholism: Clinical and Experimental Research. 2017 May;41(5):1054-1062. PubMed PMID: 28295414; PubMed Central PMCID: PMC5404970.
- Hasin DS, Wall M, Witkiewitz K, Kranzler HR, Falk D, Litten RZ, Mann K, O'Malley SS, Scodes J, Robinson RL, Anton RF. Change in Non-Abstinent World Health Organization Risk Drinking Levels and Alcohol Dependence: A 3-Year Follow-Up Study in the United States General Population. Lancet Psychiatry. 2017 Jun; 4(6):469-476. PubMed PMID: 28456501.
- Witkiewitz K, Hallgren KA, Kranzler HR, Mann KR, Hasin DS, Falk DE, Litten RZ, O'Malley SS, & Anton RF. Clinical Validation of Reduced Alcohol Consumption after Treatment for Alcohol Dependence using the World Health Organization Risk Drinking Levels. Alcoholism: Clinical and Experimental Research. 2017 Jan;41(1):179-186. PubMed PMID: 28019652; PubMed Central PMCID: PMC5205540.
- Witkiewitz, K, Falk, DE, Kranzler HR, Litten RZ, Hallgren KA, O'Malley SS, & Anton RF. Missing Data in Alcohol Clinical Trials with Binary Outcomes. Alcoholism: Clinical and Experimental Research. 2016 Jul;40(7):1548-57. PubMed PMID: 27254113.
- Witkiewitz K, Falk DE, Kranzler HR, Litten RZ, Hallgren KA, O'Malley SS, & Anton RF. Methods to analyze treatment effects in the presence of missing data for a continuous heavy drinking outcome measure when participants drop out from treatment in alcohol clinical trials. Alcoholism: Clinical and Experimental Research. 2014 Nov;38(11):2826-34. PubMed PMID: 25421518; PubMed Central PMCID: PMC4244651.
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- Falk DE, Litten RZ, Anton RF, Kranzler HR, Johnson BA, Active Workgroup. Cumulative proportion of responders analysis (CPRA) as a tool to assess treatment outcome in alcohol clinical trials. J Stud Alcohol Drugs. 2014 Mar;75(2):335-46. PubMed PMID: 24650828; PubMed Central PMCID: PMC3965687.
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- Anton RF, Litten RZ, Falk DE, Palumbo JM, Bartus RT, Robinson RL, Kranzler HR, Kosten TR, Meyer RE, O'Brien CP, Mann K, Meulien D. The Alcohol Clinical Trials Initiative (ACTIVE): purpose and goals for assessing important and salient issues for medications development in alcohol use disorders. Neuropsychopharmacology. 2012 Jan;37(2):402-11. PubMed PMID: 21900883; PubMed Central PMCID: PMC3242301.

ACTIVE Posters

- Witkiewitz K. (2023, June). Craving. Poster presented at the 46th Annual RSA Scientific Meeting, Bellevue, Washington.
- Wikiewitz K. (2023, June). AUD Remission. Poster presented at the 46th Annual RSA Scientific Meeting, Bellevue, Washington.
- Knox J. (2019, June). WHO Findings from the NESARC. Poster presented at the College on Problems of Drug Dependence 81st Annual Scientific Meeting, San Antonio, Texas.
- O'Malley SS. (2018, June). Response to Pharmacotherapy: A Comparison of Endpoints Based on Abstinence, No Heavy Drinking and Reductions in WHO Drinking Levels in Three Trials. Poster presented at the Research Society on Alcoholism Scientific Meeting, San Diego, CA.
- Hasin D. (2018, June). WHO-Defined Risk Drinking Levels and Drinking Consequences: Prospective Findings From the NESARC Waves 1 & 2 (2001-2005). Poster presented at the Research Society on Alcoholism Scientific Meeting, San Diego, CA.
- Falk DE. (2017, December). Novel Efficacy Endpoints Based on Shifts in the World Health Organization (WHO) Risk Levels of Drinking: Treatment Effects in Alcohol Pharmacotherapy Trials. Poster presented at the American College of Neuropsychopharmacology 56th Annual Meeting, Palm Springs, CA.

ACTIVE Data Presentations

- Witkiewitz K. (2023, May). Beyond Abstinence: Reductions in Drinking as an Endpoint for Alcohol Clinical Trials. Panel presented at the International Congress on Alcoholism and Stress, Volterra, Italy.
- O'Malley S. (2021, June). WHO Risk Drinking Reduction A New Endpoint for Clinical Trials. Symposium presented at the Research Society on Alcoholism Scientific Meeting, Virtual.
- Anton, R. (2021, June). WHO Risk Drinking Level: A Harm Reduction Outcome For Clinical Trials For Alcohol Use Disorder. Symposium presented at the Research Society on Alcoholism Scientific Meeting, Virtual.
- Knox J. (presenter), Scodes J., Witkiewitz K., Kranzler H., Mann K., O'Malley S., Wall M., Anton R., Hasin D. (2021, June). Reduction in WHO Risk Drinking Levels and Cardiovascular Disease: 3-year Follow-up Results in the US General Population. Symposium presented at the Research Society on Alcoholism Scientific Meeting, Virtual.
- Schacht J., Anton R. (2019, June). Prediction Of Alcohol Harm Reduction (Who RDL) Outcomes From Cue-Elicited Brain Activation In A Randomized Trial Of Naltrexone. Symposium presented at the Research Society on Alcoholism Scientific Meeting, Minneapolis, Minnesota.
- Witkiewitz K. (2019, June). Beyond Abstinence: Reductions in Drinking as an Endpoint for Alcohol Clinical Trials. Symposium presented at the College on

Problems of Drug Dependence 81st Annual Scientific Meeting, San Antonio, Texas.

- Hasin D. (2019, June). Validation of a Measure of Opioid Use Disorder Among Chronic Pain Patients Treated With Opioids. Workshop presented at the College on Problems of Drug Dependence 81st Annual Scientific Meeting, San Antonio, Texas.
- Anton RF. (2018, December) Harm Reduction as a Goal in AUD Pharmacotherapy– Role For the WHO Risk Drinking Category Change. Symposium presented at the AAAP Annual Meeting and Scientific Symposium, Bonita Springs, FL.
- O'Malley SS. (2018, June) 2018 RSA Distinguished Researcher Awardee: Beyond Abstinence: An Evolving Perspective on Naltrexone and Pharmacotherapy for Alcohol Use Disorder. Plenary presented at the Research Society on Alcoholism Scientific Meeting, San Diego, CA.
- Anton RF. (2018, June) Insights From The Design and Implementation of Medications Development Trials for Alcohol Use Disorder. Panel presented at the Research Society on Alcoholism Scientific Meeting, San Diego, CA.
- O'Malley, SS. (2018, May) ACTIVE Update: Reduction in World Health Organization (WHO) Drinking Risks Level as a Primary Endpoint for Alcohol Treatment Trials. Panel presented at the ASCP Annual Meeting, Miami Beach, Florida.
- Witkiewitz K. (2017, August). Reduction in World Health Organization (WHO) Drinking Risk Level as an Endpoint for Alcohol Clinical Trials. Symposium presented at the APA Annual Meeting, Washington D.C.
- O'Malley SS. (2017, May). The Development and Selected Performance of Patient Reported Outcomes (PRO) in Psychopharmacotherapy Trials – is the Juice Worth the Squeeze? A Review of Initiatives by the FDA, NIH, and the Alcohol Clinical Trials Initiative (ACTIVE). Panel presented at the ASCP Annual Meeting, Miami Beach, Florida

ACTIVE Press Coverage

- O'Connor, A. (2021, July 12). Alcohol Abuse Is on the Rise, but Doctors Too Often Fail to Treat It. *The New York Times*, Retrieved from https://www.nytimes.com/2021/07/12/well/live/alcohol-abuse- drinking-treatment.html?referringSource=articleShare

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