ISCTM Working Group Development of Novel Endpoints for Clinical Trials in Substance Use Disorders

ISCTM Autumn Conference, 12-13 Sep 2024, San Diego, CA, Westin Hotel

Meeting Overview

All participants introduced themselves and signed the attendance sheet, which was returned to the administrative staff. Tanya Ramey presented the current Outline for the manuscript titled "Commentary on the Development of Novel Endpoints for Clinical Trials in Substance Use Disorder". Martin Mumenthaler participated via Zoom. After the presentation, there was a discussion of key topics. The summary of the Work Group meeting was developed by Tanya Ramey and Martin Mumenthaler.

Summary and Recommendations

Based on the discussion at the meeting, the following sections and/or paragraphs will be added to the Outline:

- Epidemiology data section will be added to the Outline to show the degree of unmet medical need
- The Opioid Crisis as a public health emergency and Opioid Overdose crisis will be discussed
- A section on the FDA–led set of public meetings on Patient-Focused Drug Development for Opioid Use Disorder (OUD) and Stimulant Use Disorder (StUD) with inclusion into the meetings of patients suffering from Opioid Use Disorder and Stimulant Use Disorder respectively.
- Substance use disorder-related stigma issues and research in stigma decrease and removal will be added to the Outline.
- Specific challenges with the SUD population will be added to be discussed: unreliability of self-reported information, and extreme heterogeneity of the study population, as diagnosed by DSM-5, genetics.
- A section will be added on how to achieve the detection of beneficial impact on distal social functioning aspects of an individual with SUD. Suggestions on the development of sensitive-to-change measures capable of detecting distal functional improvements were received.
- Demonstrating distal benefits and value of decreased drug use via using the economic endpoint was suggested, such as e.g., ER visits. (This endpoint is also mentioned in the FDA Guidance for OUD)
- Using a composite endpoint as a novel endpoint approach was discussed. In a discussion, It was deemed to be challenging as an approach, as from the regulatory perspective it is being treated in the same way as a co-primary endpoint. Interpretation of composite endpoints is also challenging.

Next Steps:

- The group plans to continue periodic meetings every other month to gauge progress in working on the Outline and starting on the manuscript itself
- The group is currently preparing for a session at the 21st Annual Scientific Meeting in Wash DC on Feb 20, 2025, 2:00 PM- 5:30 PM.