Developing the First Clinical Outcome Assessment for Opioid Craving as an FDA Qualified Drug Development Tool (DDT)

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SUBMISSION DETAILS

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Methodological Issue Being Addressed Development of a Patient Reported Outcome Drug Development Tool following the U.S. FDA Guidance

Introduction The U.S. faces a devastating opioid epidemic, associated with tremendous morbidity and mortality and substantial societal and economic costs. There is an urgent need for effective medications to improve treatment outcomes. While opioid craving is predictive of poor treatment outcomes (e.g., treatment attrition, overdose, non-prescribed opioid use), there are no standard methods for assessing or treating opioid craving. This poster will describe research being conducted to develop a validated Clinical Outcome Assessment (COA) for opioid craving, following the framework outlined by the U.S. Food and Drug Administration (FDA) in their draft Guidance "Qualification Process for Drug Development Tools-Guidance for Industry and FDA Staff". This novel COA could ultimately accelerate and simplify regulatory review for an indication such as "opioid craving" within the context of use of Opioid Use Disorder (OUD). To this point, we have successfully navigated the initial stages of the FDA's Qualification Process which consists of establishing construct validity and gathering patient feedback on preliminary craving assessments.

Methods Focus Groups:
Eligible individuals across the U.S. with opioid use disorder (OUD) in treatment or seeking treatment were invited to participate in a remote, anonymous focus group discussion that focused on characterizing dimensions of opioid craving, and gathering feedback on assessment format preferences (e.g., Likert v. Visual Analogue Scale, Question v. Statement-based assessment items). Laboratory Study: A subsequent study recruited individuals in treatment for OUD to complete an in-person laboratory assessment where participants were interviewed about their craving after exposure to opioid-related cues. Participants also completed and provided feedback on the format and content of standard craving questions.

Results Focus Group:
Twenty-one focus groups (N = 88) were conducted. The most common dimensions used to describe opioid craving included "Preoccupation/Obsessive Thoughts", "Anticipation of Negative Reinforcement", "Motivation or Desire to Use", "Anticipation of Positive Reinforcement", and "Feeling a Lack of Control" which were endorsed qualitatively by 56%, 56%, 41%, 29%, and 19% of participants, respectively. Participants who were seeking treatment were more likely to describe

craving as a “Desire and Intention to Use Opioids” or “Feeling a Lack of Control.” Individuals in treatment were more likely to describe craving as “Anticipation of Negative or Positive Reinforcement” and “Preoccupation/Obsessive Thoughts”. Participants expressed a preference for Likert response options over the Visual Analogue Scale (85% v. 15%).
Laboratory Assessment:
In the laboratory study (N = 40), participants endorsed additional dimensions of craving not discussed in the focus group study, including: “Uneasiness and Tension” (23%), and “Queasiness and Butterflies” (20%). Feedback on existing craving assessments showed participants commonly indicated confusion for ‘reversed scored’ items (63%). Again, participants endorsed a preference for Likert response options (65%).

Conclusion The focus group and laboratory assessment studies with qualitative interviews collected the necessary patient-centered feedback to develop and refine a COA for opioid craving, aligning with the path of the FDA qualification process. Data from focus groups and laboratory assessments have been used identify dimensions of craving and create corresponding items within each dimension for the testable version of a new craving assessment. With feedback from the FDA, we have created a 6 dimension assessment that is to be tested for construct validity, ability to detect change, and reliability. The new testable version of the craving assessment will be shown in the poster presentation. This area of research is extremely significant because opioid craving could represent the first patient-reported outcome (PRO) that could be used in the treatment development for OUD.

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