

***Craving a New Treatment
Endpoint for Substance
Use Disorders?
Urine Luck!***



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Creating an FDA Qualified Patient Reported Outcome for Opioid Craving

Stage 1: Letter of Intent	
	Propose Concept of Interest
	Propose Context of Use
	Background Support for Measure
Stage 2: Qualification Plan	
	Updated Background Support for Measure
	Literature Review
	Concept Elicitation
	Item Generation
	Cognitive Interviews
	Reporter Input
	Expert Input
	Propose Quantitative Analysis Plan
Stage 3: Full Qualification Package	
	Results from Quantitative Analysis Plan
	Qualitative Data from Qualification Plan
	Data Sets

Craving Assessment
Patient Reported Outcome

Context of Use:

- Persons meeting criteria for mild-severe OUD
- Inpatient, outpatient treatment settings
- Laboratory, remote, clinical research settings
- Completed on electronic device

Overview of Projects/Studies to Generate a Craving Patient Reported Outcome

1 Literature Review Gather general information on craving



Craving and opioid use disorder: A scoping review

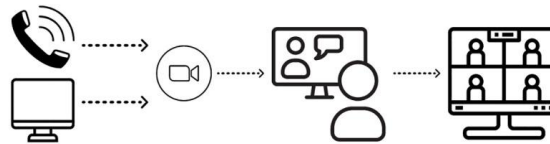
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ARTICLE INFO **ABSTRACT**
 Keywords: Introduction: The subjective experience of drug craving is a prominent and common clinical phenomenon for

- 15 Opioid craving assessments
- 4 partially validated
- Mostly adapted from alcohol, tobacco craving scales
- Variability in response option, timeframe
- Mostly single-item VAS

2 Focus Groups Gather general information on craving



1. Participant joins meeting via phone or internet.
2. Participant joins "Waiting room" until admitted into "Main session" by "Host".
Participants cannot view other attendees.
3. In "Main session" room, "Host" orients them to agenda, anonymizes their name, and ensures video is turned off.
Finally, "Host" assigns participant to "Breakout room".
4. Co-host and other anonymized participants wait in "Breakout room" until all participants have been admitted and "Host" enters.
Focus group discussion starts.



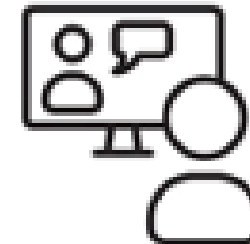
AACTION contract to develop FDA COA (Bergeria)

3 Lab Study Assess craving in the moment



R21DA054952 (Bergeria)

4 Building Assessment and Cognitive Interviews Get feedback on preliminary version



U01FD008072 (Bergeria)

What Dimensions Should Be Include in an Opioid Craving Assessment?			Final Dimensions
Most Prominent Craving Dimensions Identified in Literature Review	Focus Group Themes on the Experience of Craving	Cue Reactivity Interview Themes	

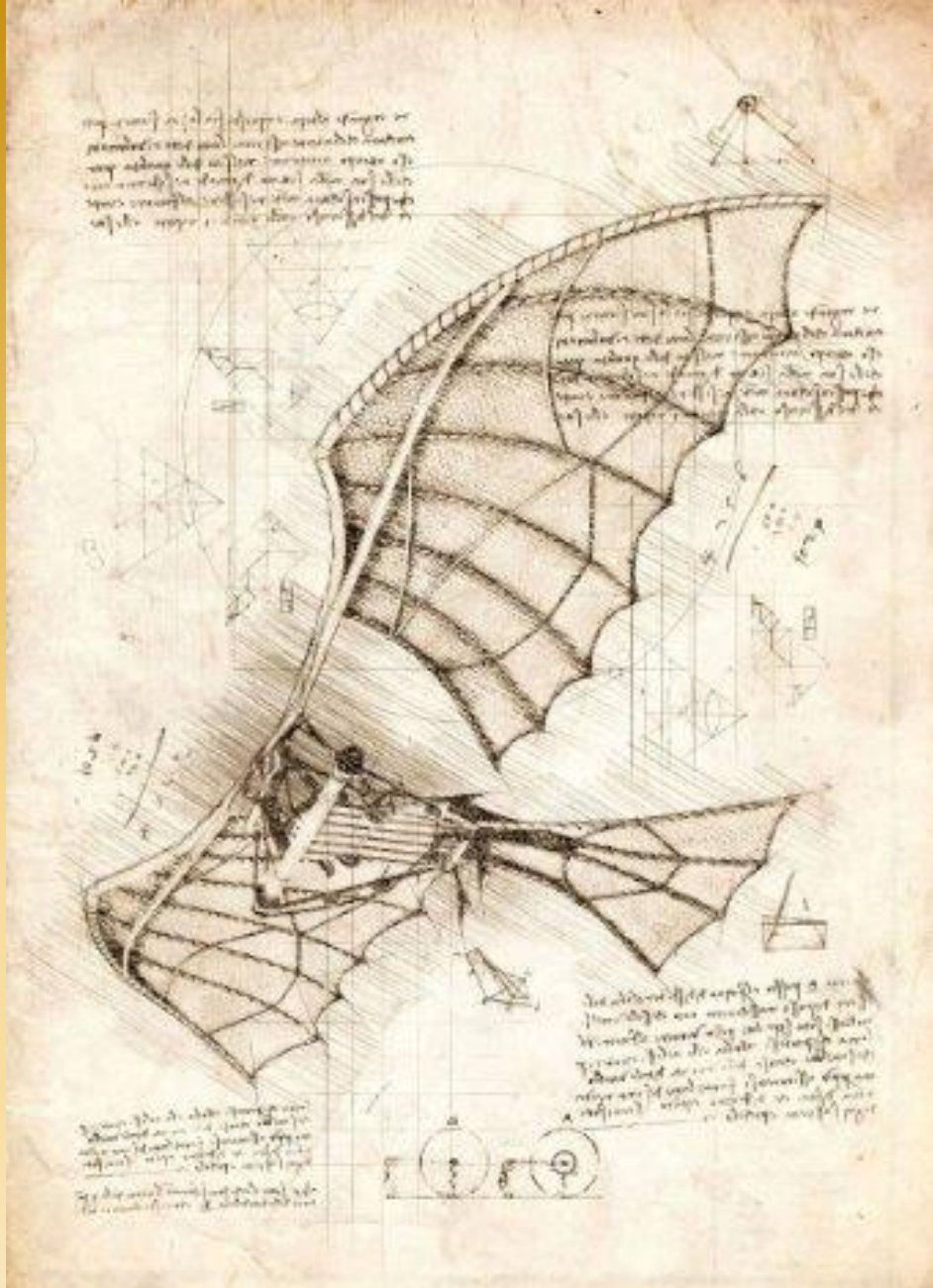
Most Prominent Craving Dimensions Identified in Literature Review

Focus Group Themes on the Experience of Craving

Cue Reactivity Interview Themes

Final Dimensions

Faceted Opioid Research Craving Assessment for Substance Use Treatment



Next Steps:

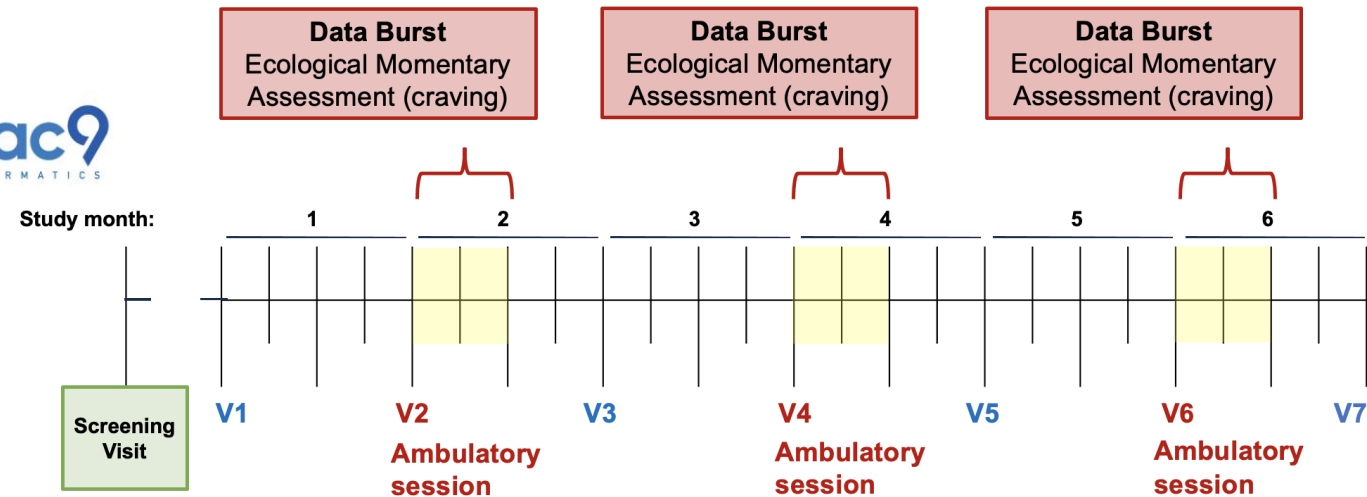
- Qualification Plan (QP) finalized and under NIH review
- UG3/UH3 funded to carry out quantitative validation plan



Jennifer Ellis, PhD



Jeannie Leoutsakos, PhD



V1 – V7 are monthly study visits to collect:

- FDA PRO craving assessment (FORCAST)
- Craving from cue reactivity task
- Urine sample collection for drug toxicology testing
- Questionnaires about health changes, and treatment updates