



INTERVEXION THERAPEUTICS

Development of a Long-Acting
Monoclonal Antibody for Treating
Methamphetamine Use Disorder

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February 2024



5.7X

Increase in US overdose deaths from 2015-2021



>1,600,000

People in the US had a methamphetamine use disorder in past year

METHAMPHETAMINE MISUSE

A Public Health Crisis

Two Main Problems

Overdose



>300,000 people/year visit a US ER

Typically present with agitation, paranoia, CNS disturbances, and/or cardiovascular issues

Methamphetamine use disorder

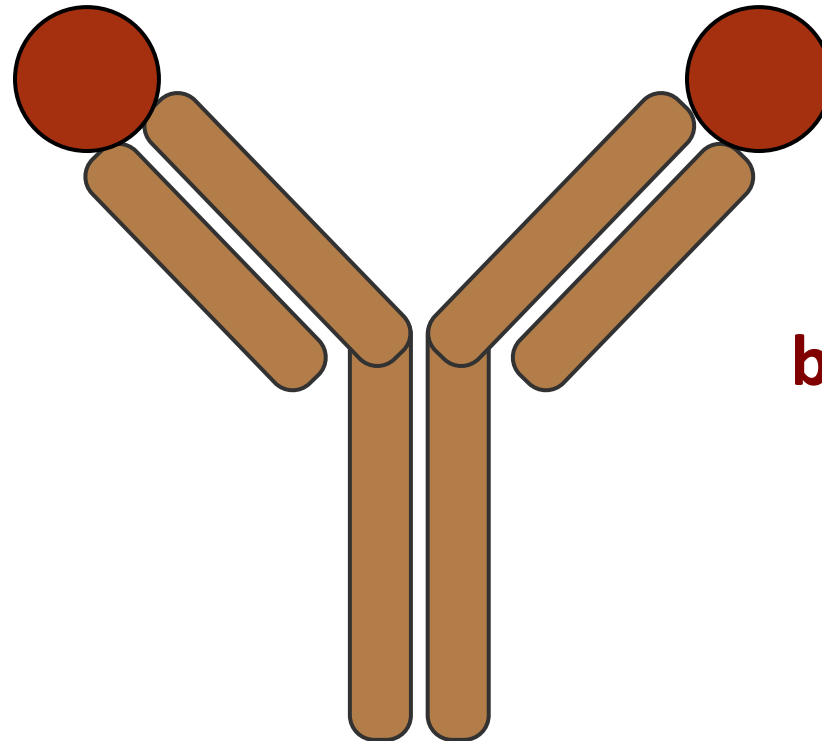


~180,000 people/year enter treatment

Population has strong motivation to overcome MUD, but the vast majority relapse within a year

A Potential Solution - Antibodies Against Methamphetamine

Antibodies bind a specific target with two arms



In this case, the arms bind methamphetamine

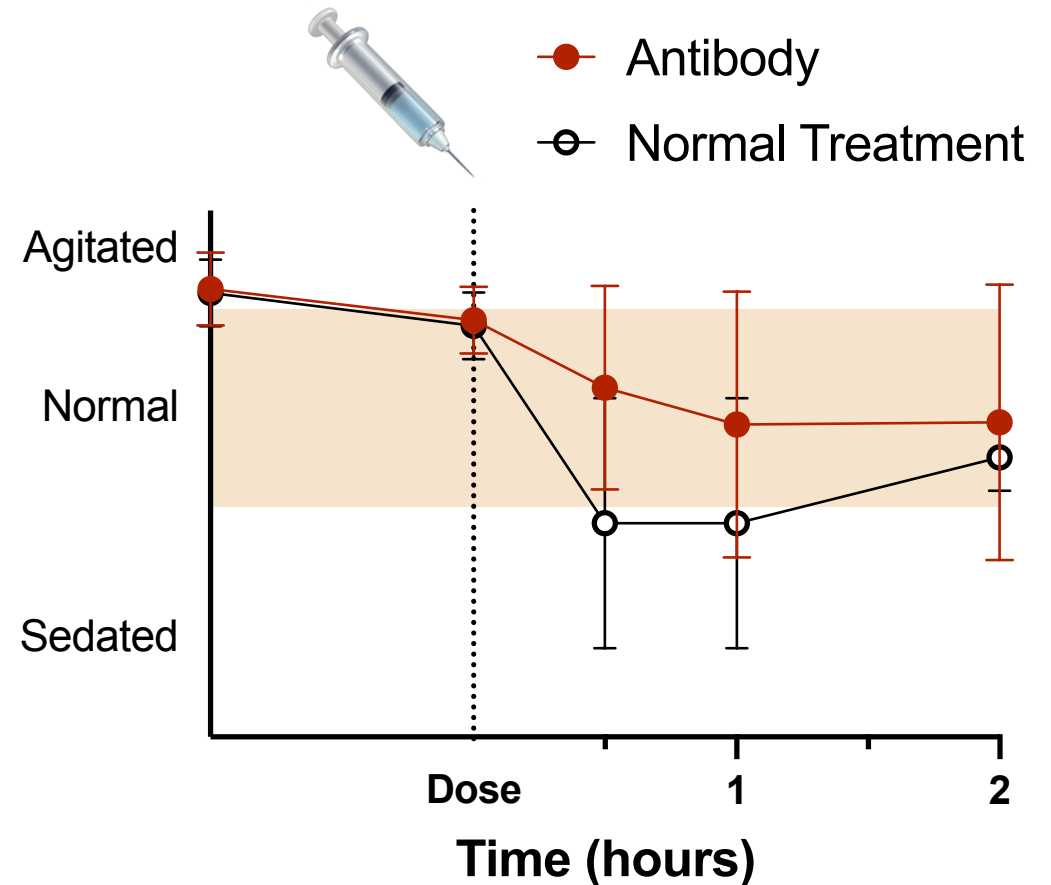
Antibodies keep methamphetamine out of the brain

Safety and Proof-of-Concept Trial in Emergency Rooms

- Patients had mild methamphetamine overdose
- Were treated with either Antibody or Normal treatment, which includes sedatives
- Were rated using an agitation scale over time

Cannot recruit patients who need treatment most

Agitation Results



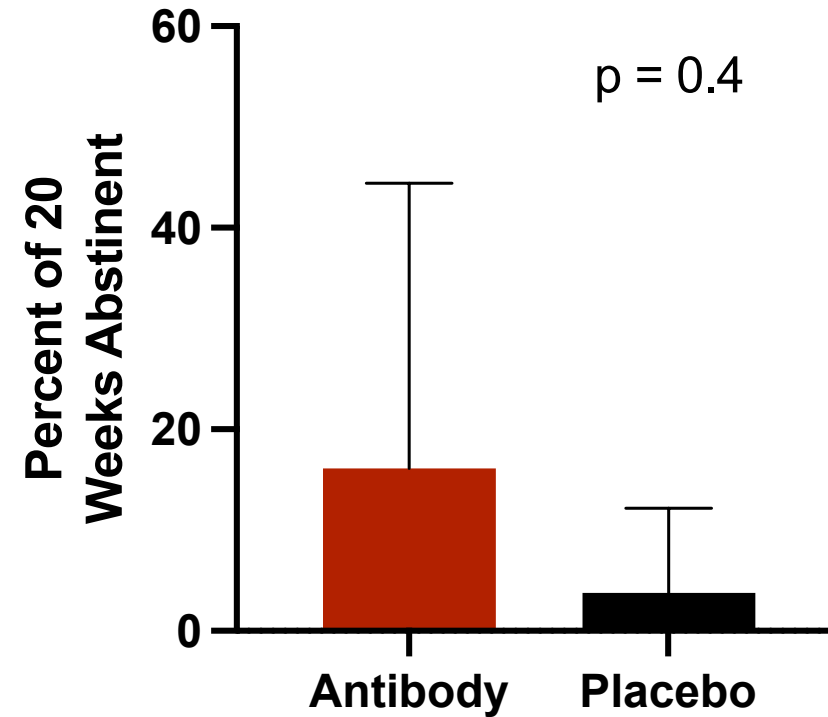


Treatment Study

- Recruited participants had methamphetamine use disorder and wished to quit using
- Treated with Antibody or Placebo for 6 months
- Tested 2X weekly for drug use
- Only ~25% completed the protocol

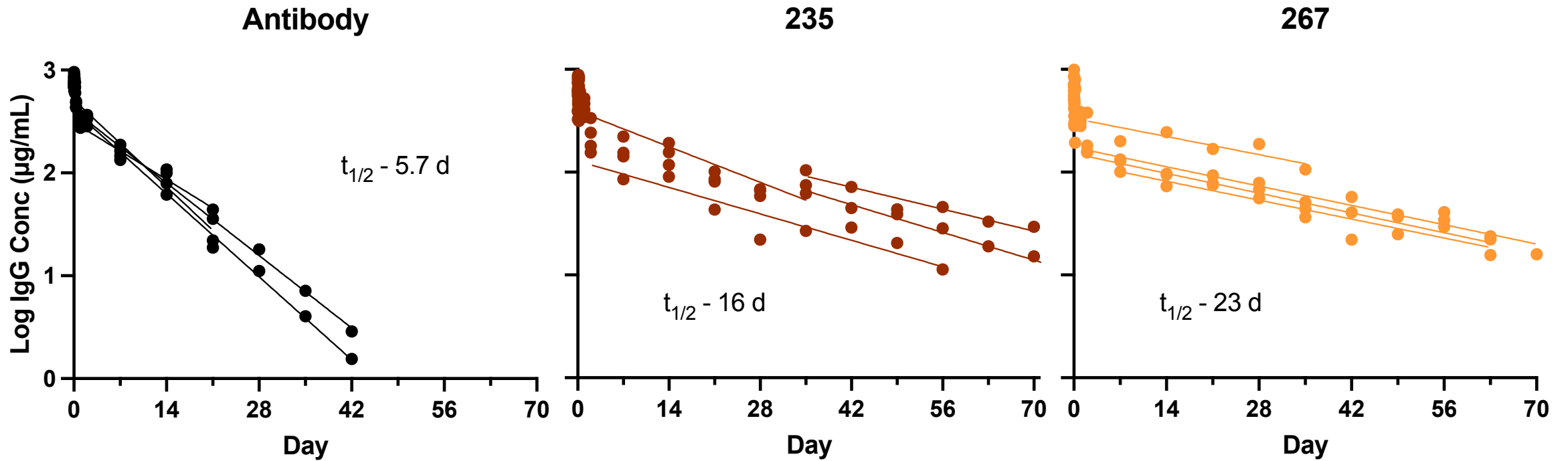
Must Improve
Protocol Compliance

Abstinence Results from Patients Who Completed the Protocol



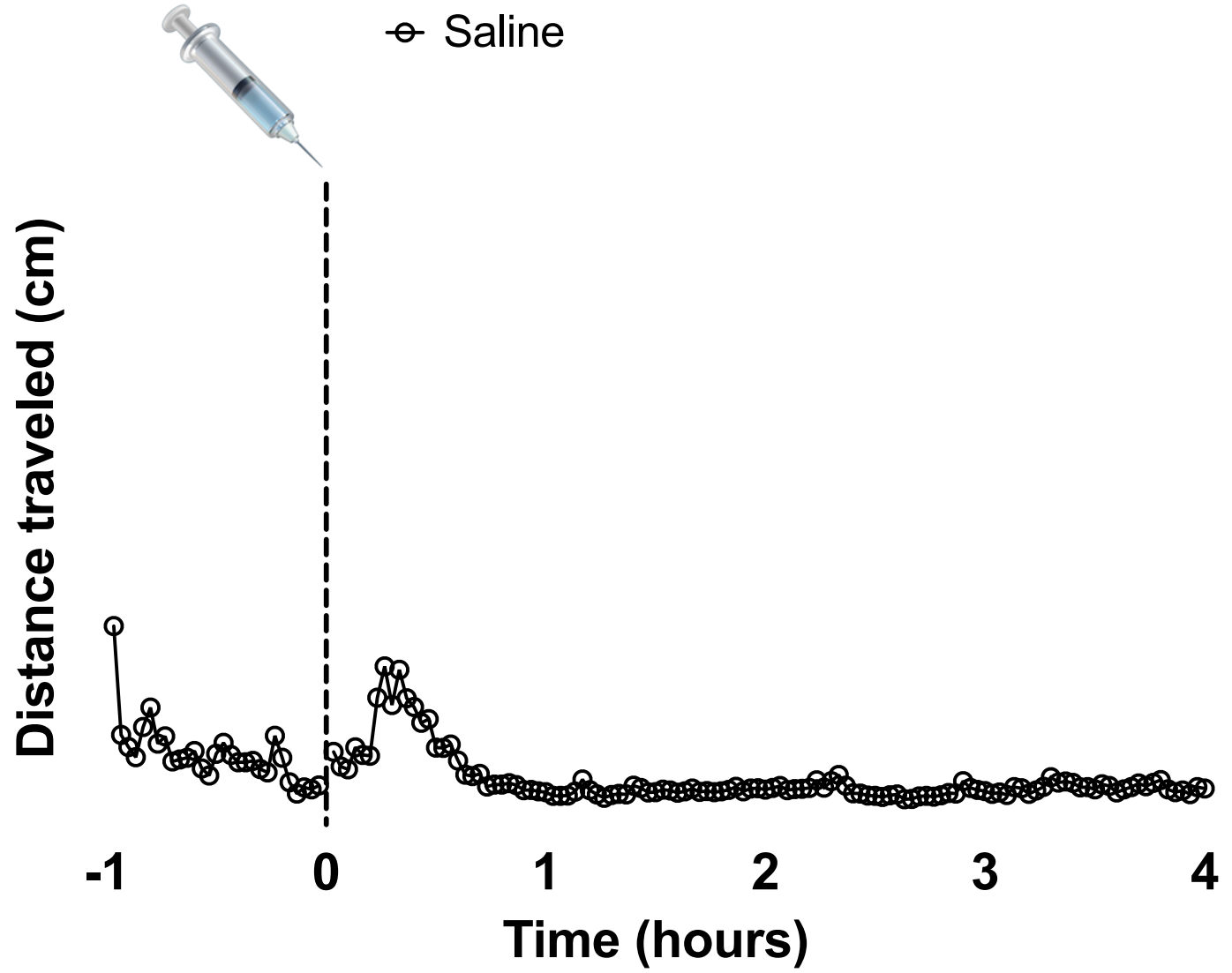
Long-Acting Antibodies

Changes to the Y-structure made antibodies that last longer

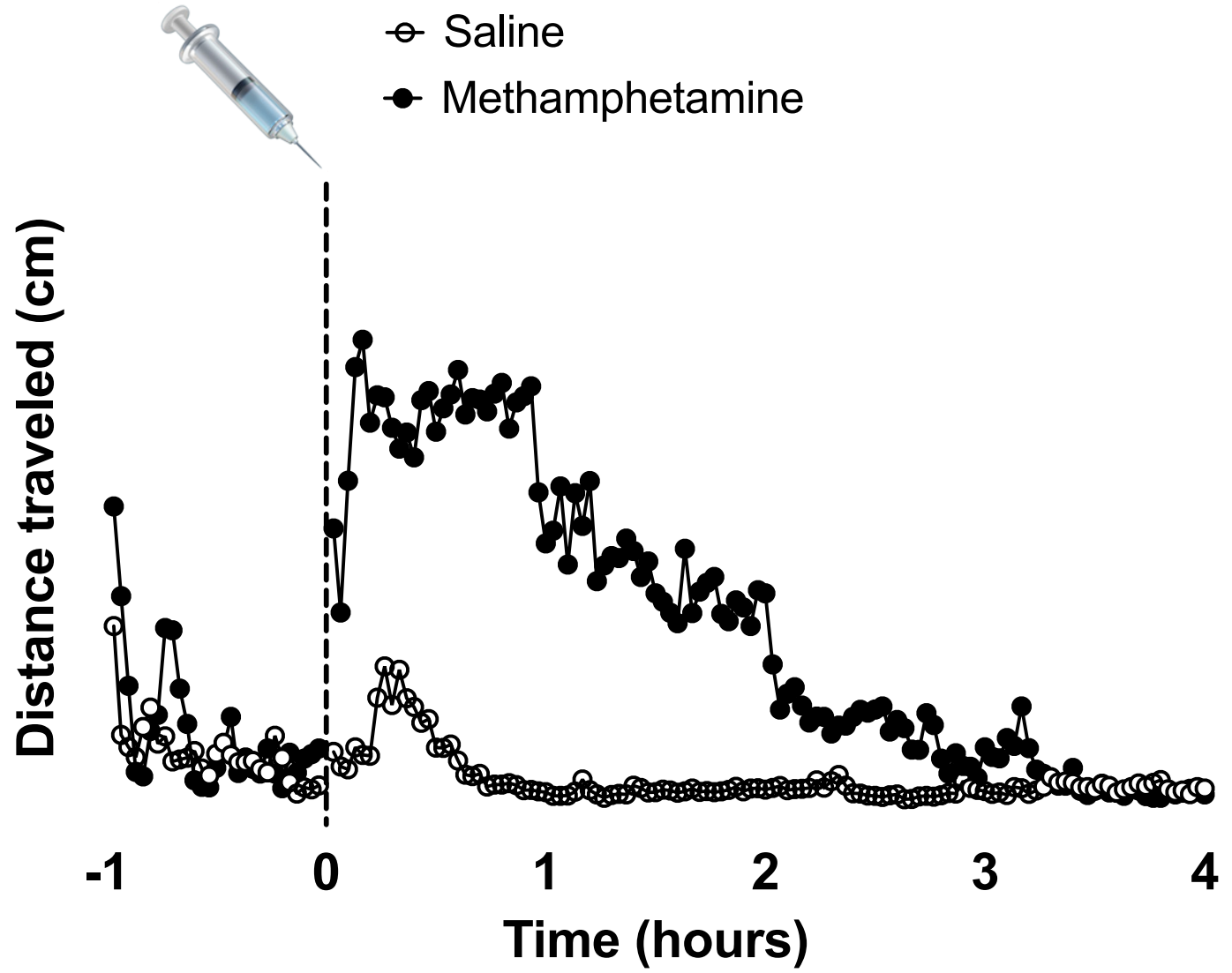


No longer need to dose 1X per month

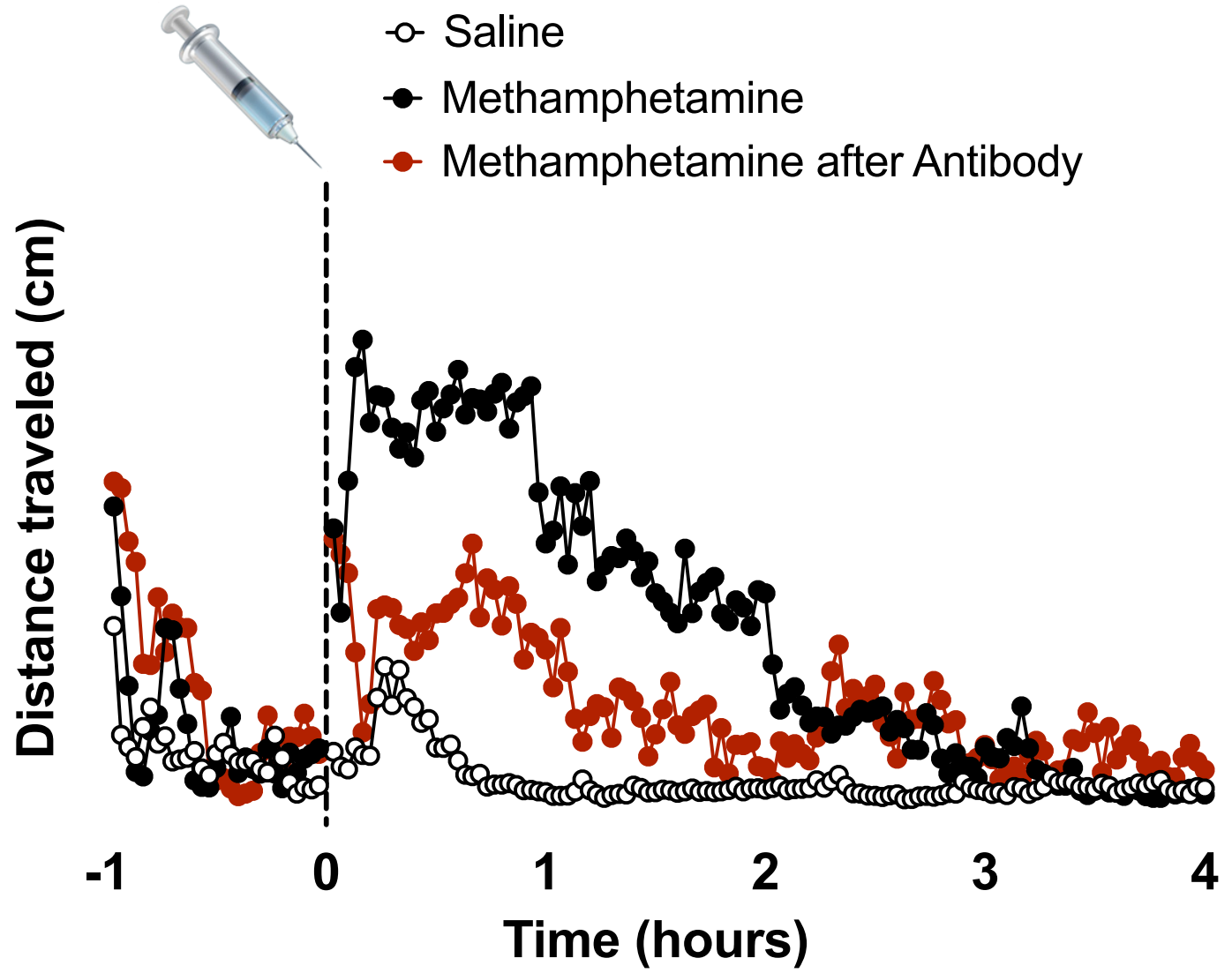
Current Studies - Antibody Testing Model



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Next Steps

Select best Long-Acting Antibody for further development

- Comparing set of 8

IXT-m200 is the most advanced new molecule

- Two decades of experience
- Gathered important insights for medications development



Challenges to Therapeutic Development

Methamphetamine overdose

- Patients that can be enrolled in trials are not those with the greatest medical need
- Cost sensitivities complicate acceptance of a new therapy beyond “sedate and wait”
- FDA does not see methamphetamine intoxication as an area of significant unmet need
 - Have declined a Fast Track request, since cheap, safe, widely-available generic sedatives are perceived to meet the medical need

Methamphetamine use disorder

- Regulatory pathway remains long, expensive, and arduous
 - Patients difficult to recruit and retain
- An acceptable endpoint other than abstinence is not readily available
 - No validated assessments to rate improvement on quality of life
 - Nothing other than abstinence has been yet shown to have clinical benefit which may be a requirement for an approval
 - Missing data are required to be positive for drug use

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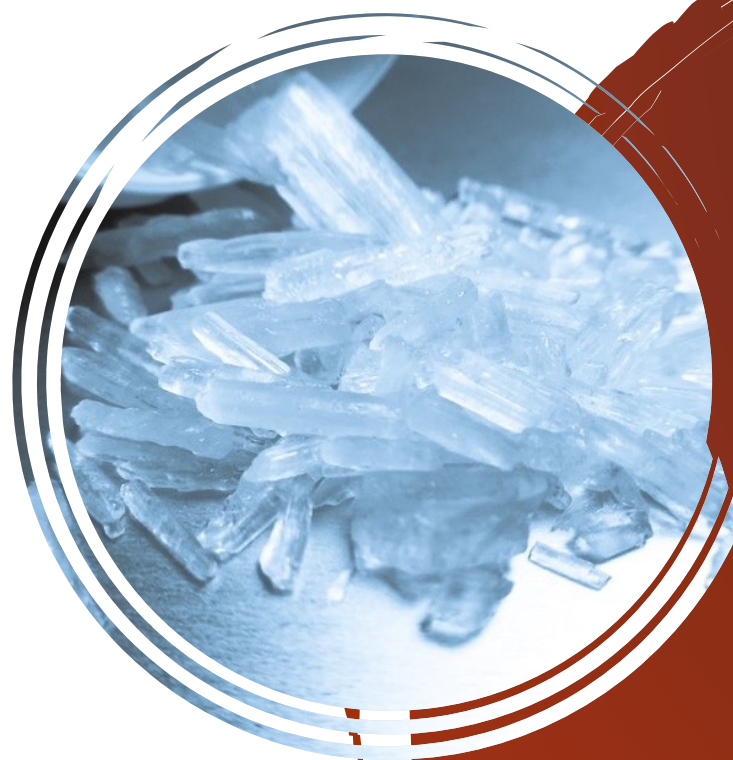
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