

**Final Recommendations of the NIAAA Extramural Advisory Board
'Medications Development'
Feb 8-9, 2005**

1. Establish a coordinated infrastructure and network of animal model laboratory testing and provide for the development of human laboratory model development.

Several paradigms of animal and human laboratory models are needed for screening of lead compounds as no one model is likely to be predictive for all facets of alcohol use disorders. Medications with known clinical efficacy should be tested in all models. A mix of established models and new models (e.g. higher throughput, primates, early stages of drinking) is needed. Human laboratory models can be a valuable bridge between animal and human studies and should be further developed. Commonality of methods and replication across sites is essential.

2. Establish a flexible and open clinical infrastructure that includes testing medications in various stages of alcohol use disorders and comorbidity using standardized core instruments.

Since many compounds are promising for multiple disorders, investigate possible collaborations with other NIH institutes in conducting clinical trials. Since most of the diagnosis of alcohol dependence occurs before the age of 26, include testing with young adults and where possible with adolescents. Establish core effectiveness assessment and standardized endpoint measurements before implementing the clinical trials network. Employ a network infrastructure for efficient use of resources and time.

3. Create a scientific advisory board that provides guidance and coordination of medications development as well as promoting translational research.

Include basic and clinical researchers on advisory board and representatives from industry.

4. Identify predictive biological and developmental markers (including DNA) for identifying patients and characterizing disease progression and treatment response to candidate medications.

Partner with high-tech companies. Use biomarkers for screening lead compounds. Explore patterns of new biomarkers using high-throughput technologies in genomics, proteomics, and metabolomics

5. Identify and validate molecular targets for medications development at various stages of the disease.

Determine molecular targets that overlap with various psychiatric and substance abuse co-morbidities. Continue to support research in identifying neurocircuits and molecular and cellular mechanisms underlying alcohol-seeking behavior and drinking that may lead to new molecular targets of drug discovery.