Day One Meeting: Objectives and Deliverables

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Objectives are a product of two CPDD conferences

• CPDD = College on Problems of Drug Dependence
  – over many years has facilitated the development and refinement of methods for preclinical and clinical ALA of psychoactive drugs

• Conferences:
  – 2003: Abuse Liability Assessment of CNS Drugs
  – 2006: Drug Formulation and Abuse Liability
Each conference had an Expert Panel

- 2003: chaired by Ed Sellers, MD, PhD
- 2006: chaired by Charles Grudzinskas
  - The Expert Panels put forth issues, recommendations, and research priorities
  - One of the recommendations coming out of both conferences and panels was a call for standardization of some outcome measures of human ALA
Abuse Liability Assessment of CNS Drugs

- Following quotes come from the two special issues of *Drug and Alcohol Dependence* that contained the proceedings of the conferences:
  - **Abuse Liability Assessment of CNS Drugs**
  - **Drug Formulation and Abuse Liability**
Researchers should be encouraged to standardize some psychometric scales (e.g., drug liking)…in order to facilitate comparisons of ALA across research laboratories and drugs. 

Investigators frequently modify assessment instruments or develop new but unvalidated scales…

– Complicates cross-study comparisons
  • Especially problematic with evaluation of new drugs for which there is uncertainty of the most appropriate methods
  • Leads to use of many similar but significantly different methods, which in turn often results in mixed results that greatly complicate interpretation
It is anticipated that it may be difficult to reach consensus on a standardized battery and even if developed, investigators may be reluctant to use such a set of assessments.

At the very least, a standardized battery could be one component of the evaluation, leaving investigators free to add other nonstandardized assessments.
2006: Drug Formulation and Abuse Liability

- Continued standardization of the primary outcome measures used in ALA should be encouraged to permit more systematic comparisons across studies.
Abuse Liability Assessment

• Focus for today is on ALA of analgesics
  – Opioids
  – Analgesic entities that appear to be mediated by CNS pathway

• Primary entities of interest:
  – Analgesics in development for FDA-approval in which ALA is a requisite
Meeting Objectives

• To present and discuss outcome measures of analgesic abuse liability assessment studies
  – Subjective effects measures
  – Cognitive/psychomotor effects
  – Physiological effects
  – Reinforcing effects

• To reach a consensus on what measures should be recommended for ALA of CNS analgesics
Meeting Deliverable

• Eventually, a manuscript published in a peer-reviewed journal
• Specifically, a consensus document outlining our recommendations for:
  • consideration of certain core outcome measures for the assessment of abuse liability of CNS analgesic drugs
  • with the recognition that these measures can be supplemented by additional measures depending on the specific objectives of the study