ISCTM
THE INTERNATIONAL SOCIETY FOR CNS CLINICAL TRIALS AND METHODOLOGY

Abuse Potential WG

- **Objectives**
  - Address clinical and regulatory aspects of abuse liability potential assessment
    - Reviewing and collecting comments on FDA's Draft Decision Tree
    - Discussing appropriate clinical methodology for assessment of abuse potential
- **Feedback**
  - Abuse potential assessment does not need to be performed chronologically
  - You should know clinical therapeutic doses before conducting preclinical and clinical abuse liability studies
  - Abuse liability assessment is not based on a single study, but on composite of data (CMC, preclinical, and clinical)
  - Evaluation of AEs of interest should include evaluation of duration, severity, and relationship to PK
  - FDA Examine clusters of AEs with other CNS and non-CNS effects
- **Next Steps**
  - WG collected initial comments but the decision tree and additional comments from ISCTM welcome through end of March 2012
  - WG Plans to submit comments to FDA in 2Q 2012
  - Explore interest of ISCTM membership in developing SMQ for abuse potential
  - Explore interest of ISCTM membership in participating in discussion regarding clinical trial designs of human abuse liability studies