Objectives

1. To overview the FDA Draft Guidance on Abuse Deterrent Opioids – Evaluation and Labeling with the focus on clinical assessment of the ADF approaches

2. To summarize the ADF Science Meeting discussions and recommendations

3. To review directions for future developments of this field.
• Two draft guidances issued by FDA to guide industry in abuse potential assessment of CNS drugs, and evaluation and labeling of abuse deterrent opioids
• Assessment of abuse potential is dynamic
  – Methodology must be adapted to drug/formulation under study
  – Data interpretation continues to be challenging
  – Not a “one size fits all” approach
  – Statistical approaches are still under debate and require further discussions
• Prevalence of abuse of other prescription drugs (i.e. stimulants) on rise
  – Studies show that stimulant abusers administer orally and intranasally
  – Potential to utilize abuse deterrent technologies for stimulants
• Efforts are underway to characterize Rx opioid abuse, misuse, overdose, death and addiction in pain patient populations
• Requires novel tools to measure such outcomes
• Adverse event assessments require additional probes in order to generate meaningful narratives for abuse potential assessment
Next Steps

• Continue dialogue around methodological approaches to abuse potential assessment with key stakeholders
• Facilitate a private/public coalition to discuss collection of abuse-related adverse event data in CNS clinical development
• ISCTM working group will support future meetings (including the Abuse Deterrence Science follow-up meeting 2014) involving scientific discussions with key stakeholders and the FDA