

# Recent Advances and Regulatory Implications in the Design and Analysis of Clinical trials utilizing PROs for Assessment of Pain and Clinical Symptoms

Invited Session 6



# Patient Reported Outcomes

- Patient-reported outcomes (PRO) are measures of a subjects' health status provided directly by the subject without intervention or interpretation by a health care professional.
- PROs are often used in the clinical trials for evaluating endpoints to detect the subject's perception of the effectiveness of a drug or device.

# Patient Reported Outcomes

- The use of PROs by regulatory authorities is being encouraged as a methodology that provides structured techniques and instruments that minimizes measurement error and ensures consistency in data collection and analysis.
- PROs that have been rigorously developed and validated often provide an unbiased assessment of the safety and efficacy of planned treatment modalities.

# Speakers

- **Best Practices for implementation and analysis of pain scale PROs in clinical trials.**
  - Nan Shao, PhD
  - Mark Jaros, PhD
- **FDA Review of Patient Reported Outcome (PRO) Measures that Support Labeling Claims.**
  - Ann Marie Trentacosti, M.D.  
Medical Officer/Endpoints Reviewer