

QT Assessment in Early Clinical Development

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ICH E14 and Afterwards

- ✓ How do perform a TQT
- ✓ Use of active controls and blinding issues
- ✓ Statistical approaches to central tendency analysis
- ✓ Parallel-designed studies
- ✓ Nested-designed studies
- ✓ Individualized corrections
- ✓ Baseline definition

PK/PD Modeling during early clinical studies- can the predictive value be similar to that of a TQT study?

Think-Tank

- Goal: to come out of the meeting with tangible plans for collaborative work that can advance the science in a measurable manner over the next 12-18 months
- Highly interactive; the key to a Think-tank is focused discussion
 - Need to stay focused on the discussion points
 - Moderator will move the topics along if needed
- Talks are short and must stay on time
- Raise card to be recognized or stand at microphone
- Break-out sessions

QT Evaluation in Drug Development



- This Think-Tank
- Several work-streams
- Significant impact using early clinical data in lieu of the TQT in certain circumstances