



# Adjudication: Practical Aspects

## Regulatory Perspectives

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## What Is Quality?

- “Trial quality is defined as the avoidance of errors that matter to decision making...” – Clinical Trials: Rethinking How We Ensure Quality. Landray et al. Drug Information Journal 2012 46:657-60.
- While sometimes requiring precision and sometimes costly, it is not:
  - Directly dependent on the degree of preciseness
  - Something that necessarily correlates with money or effort

# THE EMPEROR'S NEW CLOTHES



*Hans Christian Andersen*

# The Relationship Between Adjudication and Quality

- Adjudication is a tool that sometimes leads to quality
  - However, the cost and effort of adjudication do not magically imbue quality (the absence of errors that matter to decision making).
  - In some contexts, one may not need to adjudicate to avoid errors that matter to decision making
  - It may be possible to demonstrate quality by adjudicating a subset of data
  - It may be possible to improve quality by introducing adjudication in early phases of data collection

## Considerations when using Adjudication

- Is adjudication indicated at all to assure quality in a given trial?
- Is the goal to improve quality or to demonstrate quality?
- To achieve the goal, when during the trial should adjudication be done?
- To achieve the goal, it is necessary to adjudicate every event?

# Uses and Limits of Adjudication as a Tool to Assure the Safety of a Product



- Useful for increasing the precision surrounding events measured in a clinical trial
- Very limited ability to increase power of a trial
- Not helpful for testing new hypotheses generated during trial
- Does not ensure that only appropriate populations use the product