

Next Steps in Health Outcomes and Behavioral Sciences

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Exploring the Current State and Future Applications of IRT,
Item Banks, and CAT

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Task

- How will the pharmaceutical industry benefit by incorporating IRT, item banking and CAT?
- What demonstrations are necessary to explore the potential benefits of item banking and CATs to health outcomes measurement in clinical trials?
- What role should industry play to push this arena forward?

Perspective

- One individual working on measurement issues within one pharmaceutical company

Goals

- Discover, develop and bring to market therapeutic products that will improve the health of consumers
- Provide a reasonable return on investment to company stockholders

Potential Benefits

- Improved measurement of trial endpoints
 - Developing more efficient new measures
 - More efficient evaluation of existing measures
 - Revising existing measures to improve sensitivity to small but important differences
- Decreased burden
 - respondents and investigators
- Optimize use of existing data
 - Comparison of findings from trials that used different endpoints

What demonstrations are necessary to explore the potential benefits of item banking and CATs to health outcomes measurement?

Data must be convincing to key audiences

- Different audiences require different types of information
- Key audiences
 - Regulatory authorities
 - Patients
 - Clinicians
 - Payers

What role should industry play
to push this arena forward?

History

- History of industry sponsorship of new instruments and innovative measurement techniques
 - Instrument development, e.g., SF-36, EQ-5D, SIP
 - Innovative methods, e.g., e-PRO, formatting of PRO instruments

Barriers to Implementation

- Communication
 - Complex topic
 - Use of IRT and education terminology
- Clarification of benefit, i.e., score changes
- Access
 - Who owns the instrument or methodology?
 - Who has access how is this decided?
 - Are there legal issues that need to be resolved?

Potential Contributions of Industry

- Direct support through grants
- Data collection in large populations in longitudinal studies
- Access to existing data bases