

Item Banks and Computerized Adaptive Assessment: An Industry Perspective

Robert J. Morlock, PhD

Biogen Idec

February 26, 2008

Washington DC

- Will the pharmaceutical industry benefit from Item Banks and Computer Adaptive Assessment?
 - What hurdles need to be crossed for use in clinical trials?
 - How should industry support the use of item banks and computer adaptive assessment?
-
-

- One individual at one biotechnology company



Industry Objective

- **Develop new therapies**
- **Provide a return to shareholders**

Merck & Co.,
Where patients come first.

Pfizer Inc
**Working for a healthier world.
Life is our life's work.**

Sanofi-Aventis,
Because health matters.

Janssen-Cilag
**Your partner in integrated health
care.**

GlaxoSmithKline company
Do more, feel better, live longer.

Polpharma
People helping people.

To Meet Objectives...

- Provide different levels of evidence to key stakeholders
 - Regulatory Authorities
 - Clinicians
 - Patients
 - Payers



IRT/CAT



Benefits and Barriers

- Reduce noise
- Increase sensitivity
- Decreases patient and staff burden
- Broader comparisons across different trials

- Potential to lower trial size (lower costs)



Benefits and Barriers

- Operational/administrational hurdles
 - Communication of a complex topic
 - Clarification of ownership
 - Translations and fees
- Acceptance by regulators



How should industry support the use of item banks and computer adaptive assessment?



- Industry Sponsorship
 - Development of new instruments and translation of existing tools
 - Global Registries
 - Educational Grants



- How to operationalize use of IRT/CAT in global registration studies is a formidable task.
 - Acceptance by key stakeholders and the potential to run smaller faster trials will drive adoption.
 - Industry will help fund IRT/CAT initiatives to the degree it helps meet their objectives.
-
-

