The Emerging Role of Patient-Reported Outcomes (PROs) in Clinical Trials in India

What are PROs? PROs are patient-reported outcomes that assess how patients perceive, experience, or feel about an intervention or treatment.

What are PROs outcomes? PROs outcomes can be divided into two categories: objective outcomes and subjective outcomes. Objective outcomes are measured objectively by a third party, while subjective outcomes are measured subjectively by the patient.

Types of PROs

- Symptom-related PROs
- Health-related quality of life (HRQoL)
- Health utility
- Satisfaction scores
- Fatigue

Why are PROs important?

- Improve clinical trials for therapeutic evaluation
- To influence health policy
- To take reimbursement decisions
- To improve optimal PRO data collection

PROs in Clinical Trials: Validate Label Claims

- Inclusion of PROs in clinical trials provide valuable subjective information about health intervention
- To capture this valuable data, many pharmaceutical industries have started to include PROs routinely in their clinical trials to validate the claims of their pharmaceutical products
- USFDA issued guidance documents for industry in 2006 (updated 2009) to be followed while developing PRO instruments for supporting label claims

PROs in Clinical Trials in India

- Clinical trials in India have started to use PROs as primary outcome measures
- Indian researchers have started to realize the importance of PROs in improving the validity of their findings

Why are PROs important? PROs are important because they provide valuable subjective information about health intervention.

Conclusions

- PROs are important in clinical trials for therapeutic evaluation
- PROs outcomes can be divided into two categories: objective outcomes and subjective outcomes
- PROs outcomes can be used to influence health policy and to take reimbursement decisions
- PROs outcomes can be used to improve the validity of clinical trials

References