What are Patient Reported Outcomes (PROs)?

USFDA: A PRO is any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else.  

Types of Clinical Outcomes to a Treatment 2

PROs in Clinical Trials: Validate Label Claims

Inclusion of PROs in clinical trials provide valuable subjective information about health status.

To capture this valuable data, many pharmaceutical industries have started to include PROs routinely in their clinical trials to validate the claims of their 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 utilise PROs as primary outcome measures.

Indian researchers have started to realise the importance of PROs in improving the validity of their findings.

Why are PROs important?3

Traditionally healthcare decisions are based on disease-centered data that is almost always doctor-reported.

South Indian tradition centers is to find a system, rather than the subjective feeling of improvement: laceration.

This lacuna can be overcome by supplementing with patient-centered data which are patient-reported.

PROs include:

- Satisfaction scores
- Symptom relief
- Well-being
- Productivity assessment
- Intervention-induced problems

PRO data are especially important in chronic disabling conditions where improvement in patient suffering forms the most important aspect of therapy.

PRO data may be used:

- To inform clinical care and therapeutic decision making
- To take reimbursement decisions
- To predict long-term outcomes
- To influence health policy

PROs in Clinical Trials1

1. In many clinical trials, PROs are among the primary (rather than secondary) effectiveness endpoints.

2. PROs are required to be shown in CTs by pharmaceutical companies in order to validate their label claims.

PROs in Clinical Trials: Effectiveness Endpoints4

- PROs, including health-related quality of life (HRQoL), symptoms such as pain or fatigue, and health utility, are increasingly assessed in clinical trials as a measure of effectiveness.

- Especially in clinical trials which evaluate conditions such as irritable bowel syndrome, migraine, pain, insomnia, asthma, psychiatric disorders, oncology endpoints, etc.

- However, the quality of PRO data can suffer in many trials because of high rates of missing data and inconsistencies in data collection.

- This adversely affects the integrity and usefulness of such data in clinical practice.

- Despite the importance of PROs, studies suggest that protocols provide little guidance regarding PRO aspects of the trial.

- This leads to ambiguity and significant inconsistency in PRO data collection, analysis and reports.

- To improve optimal PRO data collection, study protocol should be equipped with adequate PRO items including specific instructions about PRO data collection.

REFERENCES


