

Patient Reported Outcomes

The session will begin with a brief discussion of what patient reported outcomes (PROs) are and how they relate to other outcome measures in clinical trials. Next a brief history of CTG's involvement in the use of PROs will be presented.

Four main ways of assessing PROs will be described and distinguished: 1) instruments designed to capture multidimensional aspects of health status and quality of life; 2) modules used in specific settings 3) instruments designed to summarize health status as a single number; 4) collections of questions aimed at enabling patients to report directly symptoms and adverse effects of treatment.

Four key considerations that arise when PROs are incorporated in trials will be discussed: 1) Instrument selection; 2) frequency and timing of assessments; 3) addressing the missing data problem 4) method of analysis.

Finally, future directions and available resources will be described.

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