

HRQoL results are typically used as a secondary endpoint, but rarely as a primary endpoint. In symptom management trials, HRQoL results are usually used as a secondary endpoint, and are sometimes used as a primary endpoint. Hauser and Walsh (19) describe various categories of HRQoL scales.

The importance of HRQoL endpoints can increase where the study drug does not much influence endpoints involving survival. In other words, if the study drug and the active control drug show no significant difference in terms of halting tumor growth, in reducing the rate of metastasis, or in enhancing survival, data from HRQoL instruments can be a deciding factor in gaining regulatory approval for the study drug.

Di Maio and Perrone (20) as well as Frost and Sloan (21) find that HRQoL data are particularly helpful when two treatments result in similar survival outcomes but exhibit differences in quality of life outcomes. In other words, where the clinical efficacy of two drugs is found to be equivalent, there is little question that a prospective patient would like to know if one of the two drugs is more associated with favorable outcomes that are measured by the parameters of depression, anxiety, self-esteem, or hopefulness.

IV. SCHEDULING THE ADMINISTRATION OF HRQoL INSTRUMENTS

HRQoL questionnaires can be administered a set number of days or weeks after randomization (independently of treatment schedules), or they can be administered to coincide with treatment cycles (22). In chemotherapy involving several courses of treatment (rounds of treatment), assessments are usually scheduled to take place immediately before the next course of treatment. Coupling the time of the HRQoL with treatment time, rather than a set calendar time, is useful. If the HRQoL questionnaire is required to be administered shortly before each round of chemotherapy, the investigator can be assured that the HRQoL instrument will only capture data relating to chronic conditions of the patient. But if the HRQoL instrument is tied to specific calendar dates, and where dates of chemotherapy for some patients need to be rescheduled, the result is that the HRQoL instrument will capture chronic characteristics for some patients, and acute characteristics of other patients. In other words, if the investigator prefers that HRQoL data be acquired shortly prior to a round of chemotherapy, but where chemotherapy for a given patient needs to be rescheduled a few days earlier, a calendar-based HRQoL instrument will inadvertently capture the acute effects of the chemotherapy.

¹⁹ Hauser K, Walsh D. Visual analogue scales and assessment of quality of life in cancer. *J Support Oncol*. 2008;6:277–282.

²⁰ Di Maio M, Perrone F. Quality of Life in elderly patients with cancer. *Health Qual Life Outcomes*. 2003;1:44.

²¹ Frost MH, Sloan JA. Quality of life measurements: a soft outcome – or is it? *Am J Manag Care*. 2002;8:S574–S579.

²² EORTC Quality of Life Group. *Guidelines for Assessing Quality of Life in EORTC Clinical Trials*. Brussels, Belgium: EORTC; 2002 [32 pages].