interventions, optimal allocation decisions are derived, hypothetically assuming a market context.

**RESULTS:** vNM utility functions are developed for the alternative treatments and a “no treatment” option (T0) on the basis of outcome and probability data from clinical research. Utilities of procedures and outcomes can be identified empirically. This requires a preference ordering of treatment alternatives and MSG questions relating to hypothetical treatments. The number of MSG questions and hypothetical treatments (n-2) depends on the number of vNM variables (n). This procedure identifies the ratio of marginal utilities of T1 and T2, dT2/dT1. The inclusion of relative prices of T1 and T2, pT1/pT2, into the model allows the prediction of utility-based treatment choices and the application of the model in resource allocation.

**CONCLUSIONS:** The main advantages of this model are its ability to predict utility-based decisions incorporating risk preferences and to avoid the need for methodologically delicate techniques such as sensitivity analysis and discounting. The practical benefits of this approach remain to be determined within empirical evaluations.

**PMI28**

**ELECTRONIC DATA COLLECTION OF PATIENT-REPORTED OUTCOMES**

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Technological advances have resulted in Electronic Data Collection (EDC) increasingly replacing traditional paper and pencil questionnaire data collection of clinical trial data, including Patient Reported Outcomes (PRO). Our objective was to assess EDC compared to traditional methods of PRO data collection to assist in selecting a method.

**METHODS:** A literature search identified EDC-related publications within the last 5 years; a web search identified regulatory and institutional guidance documents.

**RESULTS:** Of 584 articles identified, approximately 60 articles using EDC to assess PRO data were selected for full review. Four forms of EDC were identified: personal digital assistants (PDAs), personal computers (PCs), interactive voice response (IVR) systems, and electronic mail. PDAs, PCs, and IVR may offer higher data quality than pencil and paper; data entry can be immediate, logic checks can be incorporated, thus reducing the number of data queries. Compliance with data collection protocols has been shown to be higher using EDC and evidence indicates patients and clinicians prefer it. All methods require back-up and security procedures to ensure data integrity. Studies examining EDC costs have consistently found paper and pencil methods more expensive especially as volume increases. PDAs, PCs, and IVR have been used in clinical trials to assess PROs but email lacks anonymity thereby making it unsuitable. Ecological momentary assessment (EMA) is real-time or scheduled assessment of PRO; patients are prompted to complete assessments in their current environment. EDC facilitates EMA data collection and enhances data volume and quality. The FDA requires extensive documentation of audit trails, but has not released requirements for EDC procedures.

**CONCLUSIONS:** EDC demonstrates advantages for the collection of high quality data quickly. As new technologies proliferate, clinical trials can take advantage of EDC to enhance data quality and reduce trial-related costs with precautions to ensure data security.

**PMI29**

**PATIENT-GENERATED OUTCOMES: FAD OR HERE TO STAY?**

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Patient-generated outcomes attempt to capture the individualistic nature of quality of life. Although this is an attractive concept, a critical review of these instruments is needed to assess their applicability in a clinical trial setting.

**OBJECTIVE:** To provide a critical review of four patient-generated quality of life instruments: Patient-Generated Index (PGI), Schedule for the Evaluation of Individual Quality of Life (SEIQoL), Repertory Grid, and Asthma Quality of Life Questionnaire (AQLQ).

**METHODS:** We conducted a systematic literature review of available computerized databases, the Quality of Life Research Journal and consulted experts in the field. We abstracted data from the studies and constructed a matrix comparing the four instruments based on their psychometric properties and current use in quality of life research.

**RESULTS:** The PGI and SEIQoL have been shown to be reliable and valid in several different patient populations and disease states; however, neither have been used in a clinical trial. The SEIQoL-DW, in addition, has been shown to be practical and acceptable to patients. The Repertory Grid has been shown to be reliable, valid and practical, but has only been used in one observational study. The AQLQ is a disease-specific instrument that is only partially patient-generated. It has not only shown to be reliable, valid and practical, but has also been used in clinical trials as a sole measure of quality of life.

**CONCLUSION:** Patient-generated outcomes may not be generally useful in a clinical trial setting. However, hybrid instruments, such as the AQLQ, may be applicable in a clinical trial setting. The primary role of patient-generated outcome measures is as an adjunct measure or to guide individual patient treatment decisions.