product’s value are the economic and humanistic consequences of the new therapy relative to the gold standard. However, in many circumstances, the patient is unable to provide an accurate assessment of healthcare resources consumed or their quality of life and functional status. Researchers have opted for the use of proxies in these instances, under the presumption that a larger sample size increases the power to detect meaningful differences. This presumption, however, neglects the inaccuracies inherent in proxy reporting and thus may inhibit the reliability of the estimates obtained. This workshop will review and evaluate the use of proxy respondents in the collection of resource utilization and quality of life data. A critical examination will be given to their potential influence on study results. Suggestions for overcoming these issues will also be presented and discussed. This session is directed at individuals in pharmaceutical firms, contract research organizations (CROs), and consultant companies responsible for the design and conduct of pharmacoeconomic evaluations.

HEALTH STATUS AND QUALITY OF LIFE MEASURES IN INTERNATIONAL CLINICAL RESEARCH
Marquis P1, Abetz L1, Conway K2, Mear P1
1MAPI Values, Lyon, France; 2MAPI Research Institute, Lyon, France

Assessing the impact of disease and the effect of treatment on patient quality of life (QoL) has become of major importance both to the pharmaceutical industry and the medical profession. The last 20 years have seen the development of a large number of QoL questionnaires, increasingly being used in clinical trials, with a growing emphasis on multinational applications. As a result, there is a continually expanding need for cross-nationally and cross-culturally valid, reliable and responsive QoL instruments. This course will provide key information and operational solutions to implement health status and QoL measures in clinical trials. The content of the course will cover definitions of health status and QoL; types of instruments used, including their strengths and weaknesses; identification of concepts to be measured; and selection of relevant instruments. The second part of the course will focus on strategy for instrument development, linguistic validation and psychometric validation, as well as interpretation guidelines. Participants will acquire a common baseline understanding of health and QoL evaluations, allowing them to become actively involved in development of optimal programs for clinical development and marketing purposes.

TRACK 4: STUDY METHODS

ESTIMATING DRUG EFFECTS: FROM CLINICAL TRIAL RESULTS TO ACTUAL PRACTICE
Caro JJ1, Migliaccio-Walle K1, Thizon de Gaulle I2, Coniglio A2
1Caro Research, Concord, MA, US; 2Bristol-Myers Squibb, Princeton, NJ, US

An important element in judging the worthiness of a new drug’s effects is the translation of randomized trial results to actual clinical practice. A key input is the risk experienced by routinely managed patients. The risk rate is important, because the relative risk reduction typically estimated in trials only gains meaning when it is applied to such a reference risk. While the relative risk reduction is widely believed to be generalizable, the reference risk is not. In this workshop, an ongoing study, CAPRA (CAPRIE Actual Practice Rates Analysis) will be used as a case study—along with other published reports—to examine why considering information beyond that obtained in a clinical trial can be critical in assessing the value of a new therapy. The major reasons practice may diverge from trials, along with evidence of this fact, will be introduced. The methods for extending trial results to clinical practice will be demonstrated and discussed, along with alternative approaches to estimating actual practice results from clinical trial experience. The focus will be on the use of epidemiologic studies and databases such as that from Saskatchewan Health. Details of this analysis of records for 12,931 patients used to estimate the risk of first subsequent ischemic events (MI, ischemic stroke, vascular death) in actual practice will be shown. The magnitude of the distortion, with special reference to numbers needed to treat, and the implications for cost-effectiveness analysis will be presented. All available information and methods ought to be employed when considering a new therapy, as it is insufficient to evaluate a new therapy based on trial results alone.

ESTIMATING POPULATION BUDGET AND HEALTH IMPACTS OF NEW TREATMENTS
Mauskopf JA
Research Triangle Institute, Research Triangle Park, NC, US

Most pharmacoeconomic studies present estimates of the impact of new treatments on expected lifetime costs and health outcomes for typical individuals with a given disease. However, national or local healthcare decision-makers also need to know what impact the new treatment will have on their annual budgets and on annual health outcomes for their patient populations. In this workshop, a method for estimating the population impacts of new treatments is presented. How information about the impact of a new treatment on individual patients can be combined with information about the number and type of patients in the patient population to esti-