lary committee members. **METHOD:** We addressed the issue in two steps: First, we developed guiding principles which should be evidence based, applicable, and credible, and second, we proposed a method called randomized clinical trial (RCT)—matched-arm comparison to establish therapeutic equivalence where the application of the appropriate statistical tests, as well as the a priori definition of the clinical meaningfulness of the results is stressed. **RESULTS:** The guiding principles stress the following domains with respect to study selection: The literature search, the definition and comparison of the population parameters such as the pathologic condition, inclusion and exclusion criteria, baseline characteristics, placebo response, the drugs, the outcome, and issues such as drug safety, potential of drug-drug interactions and potential compliance issues. Once appropriate RCTs have been identified and comparability is established, the primary endpoints of the two treatment arms of the two RCTs are compared through statistical equivalence tests using a priori defined meaningful differences for clinical endpoints. **CONCLUSION:** The application of the principles and the RCT-matched-arm comparison should lead decision-makers to applicable valid decisions based on unbiased results, with accurate, reproducible comparisons and predictable clinical results.

PMDM3

PROJECTING ECONOMIC RESULTS OF A EUROPEAN TRIAL TO THE UNITED STATES: ISSUES AND METHODS

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OBJECTIVE: Many pivotal clinical trials include an economic component. Because of cost and logistic constraints, trials are rarely conducted in every nation where the product will be marketed. For that reason economic results obtained in one nation ("source") are often presented to decision-makers in another nation ("target"). Information may be seen as more relevant if findings from the source nation are projected to the target nation. Study objective was to identify sources of cross-national variation in the cost of an episode of care, approaches to adjust variation, and practical problems in trans-national adaptation of economic clinical trials. **RESULTS:** We present a case study based on analysis of economic endpoints from the Donepezil Nordic Family Impact Study. Through literature review and experience, we identified four potential components of transnational cost variation: 1) relative prices for services (i.e. primary care office visit fee relative to price for chest X-ray), 2) quantity of resources (i.e. length of stay for similar hospital admission), 3) inputs to health production (certain procedures/services are performed in one nation but do not exist in the other), and 4) patient population (case definition and patient demographic characteristics). Approaches to addressing each source of variation include 1) substituting unit prices of the target country, 2) adjusting observed resource quantity to typical treatment pattern of the target country, 3) replacing selected treatment encounters with functionally analogous service existing in target country, and 4) sub-setting original trial cohort to obtain outcomes in a patient population representative of the target country. **CONCLUSIONS:** Adapting a pharmacoeconomic study is a process of modifying empirical data. The sequence of adjustments represents a progressive trade-off between internal validity (reliance on empirical data) and external validity (replication of the target country environment). Transparency enhances credibility of this process by demonstrating the separate effect of each category of adjustment.

PMDM4

MEASUREMENTS OF HEALTH STATUS IN DENMARK

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OBJECTIVE: There are three main aims of this study. (1) To create a profile of the state of health in the Danish population.For this purpose we selected three multi-attribute classification systems: EQ-5D, SF-36 and 15D. The selection of instruments was based, inter allia, on the availability of validated Danish versions and on the instruments being used internationally. (2) To evaluate the instruments in terms of their validity and reliability in measuring a population's health status. (3) To compare the instruments in the measurement and evaluation of health-related quality of life. **METHODS:** The study is based on postal questionnaires, performed by a professional survey institute. A random sample of around 6.000 individuals of the Danish adult population was contacted by phone, asking whether they would be interested in completing the questionnaires. Around 5.000 agreed to participate, and 3.400 responded (a response rate of 68%). The questionnaires contained all three instruments, including the complete EQ-5D VAS scaling exercise. A randomized experiment with 6 versions of EQ-5D containing varied wording and response categories was also embedded in the study. **CONCLUSION:** This study will provide a rich data set, the analysis of which should be an important contribution to the measurement and valuation of health-related quality of life both in Denmark and in the wider international context.

MULTIPLE DISORDERS—EYE/EAR/SKIN DISEASE

PMDE1

SOCIETAL IMPACT OF LOST EARNINGS ASSOCIATED WITH AGE-RELATED MACULOPATHY

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