

WORKSHOP OBJECTIVE: The purpose of this workshop is to enhance decision-making skills by successfully applying pharmacoeconomic assessments and the examination of outcomes research specific to the community healthcare facility.

PARTICIPANTS WHO WOULD BENEFIT: Healthcare professionals and decision-makers who provide healthcare from community healthcare facilities.

Community healthcare providers can greatly enhance patient focused and economic outcomes by performing their own pharmacoeconomic and outcome studies. Most community healthcare facilities make decisions based upon other previous studies that may not reflect their patient population, community or economic model. This workshop will enable the participant to identify and obtain vital information that is specific for their facility and patient population. Incorporating this data into the decision process will result in developing policy that is more effective for their facility and community.

WMM5

USING EPIDEMIOLOGIC DATABASES TO EXTRAPOLATE LONG-TERM OUTCOMES FROM SURROGATE MARKER DATA

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WORKSHOP OBJECTIVE: The purpose of this workshop is to review the methodological issues involved in the development of pharmacoeconomic models for preventive interventions or chronic disease treatments when the drug's effects are observed over relatively short time frames (as in most clinical trials).

PARTICIPANTS WHO WOULD BENEFIT: Researchers who want to understand how external sources of epidemiologic data can be used in conjunction with "surrogate marker" data from clinical trials to infer long-term patient outcomes.

The extended duration of follow-up in large-scale "event" trials permits researchers to document a drug's proximal effects on key biologic measures or "surrogate markers" and to attribute improvements in long-term patient outcomes to the drug's effect on the surrogate marker(s). While the ability to link short-term effects with long-term outcomes within a clinical trial is desirable, such studies are frequently cost-prohibitive. Despite the lack of long-term follow-up in traditional drug efficacy trials, it is still possible in many cases to make inferences about a drug's long-term effects on patient outcomes. In this workshop, we will illustrate how statistical models of the relationship between surrogate markers and outcomes can be developed using epidemiologic databases, and how these models can be used in conjunction with surrogate marker and cost data to estimate long-term clinical and economic consequences of drug therapy. The importance of appropriate patient identification and selection criteria in epidemio-

logic research will be stressed. A case study will be presented in which cardiovascular risk equations derived from the Framingham Heart Study database are used to estimate reductions in cardiovascular event occurrence over 1-, 5-, and 10-year time horizons resulting from decrements in diastolic blood pressure (a common surrogate marker in clinical trials of anti-hypertensive medications).

WMS2

PITFALLS WHEN USING REGRESSION EQUATIONS TO ESTIMATE TREATMENT IMPACT IN ACTUAL PRACTICE

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WORKSHOP OBJECTIVE: To demonstrate how regression equations should and should not be used when estimating the impact of treatment in actual practice.

PARTICIPANTS WHO WOULD BENEFIT: Researchers interested in using regression equations in economic models.

Short of local trials, researchers often resort to using risk equations, derived from large epidemiological or clinical studies, to forecast the costs and health consequences of a new treatment in their target population. In many cases, the mean risk factor values for the target population are included directly in the risk equation to calculate the "average" likelihood of disease for that population. This common approach may however not be justified, as we will demonstrate in this workshop, using examples based on the West of Scotland Coronary Prevention Study. The results derived in this way do not properly reflect the clustering of risk factors in the population and are very liable to give incorrect outcomes. Instead, epidemiological studies that contain information on the joint risk factor distribution in a large number of patients, representative of the target population, should be identified. These patient level data should be used to simulate individuals one at a time and the average risk for the cohort should be derived as the mean of the individuals' results. Despite the increased effort required, this is the only proper technique to accurately predict the effects of treatment in a population different from the one used to derive the equations.

WMS5

ASSESSING THE GENERALIZABILITY OF THE RESULTS OF MULTINATIONAL TRIALS FOR INDIVIDUAL COUNTRIES PARTICIPATING IN THE TRIAL

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WORKSHOP OBJECTIVE: The purpose of this workshop will be to discuss methods for evaluating the generalizability of results from multinational trials. We will