CALL FOR ABSTRACTS

Abstract Submission Deadline: January 7, 2008

Early Registration Deadline: April 1, 2008

ISPOR 13th Annual International Meeting
Sheraton Centre Toronto
Toronto, Ontario, Canada
May 3-7, 2008

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FOR FURTHER INFORMATION: WWW.ISPOR.ORG
**GENERAL INFORMATION**
- Research abstracts (except Methods and Concept abstracts) must be organized as follows: OBJECTIVES: METHODS: RESULTS: CONCLUSIONS:
- Research on all diseases is considered. Study methods include, but are not limited to, conjoint analysis, large database analysis, quasi-experimental analysis, literature or record review, modeling, naturalistic (observational) studies, randomized clinical trials, surveys.
- Research on all health care interventions is considered including drugs, behavioral modification, disease prevention, gene therapy, medical device, screening, diagnostic procedures, dietary, health education, radiation therapy, and surgical procedures.
- Reviews or methods papers are also considered as research abstracts.
- Accepted abstracts will be published AS SUBMITTED in Value in Health and distributed at the Meeting. Changes to abstracts will not be accepted after the Submission Deadline. Therefore, they should be carefully written and edited prior to submission.
- Research that has been published or presented at any national or international meeting prior to this meeting is discouraged.
- Research RESULTS must be included for an abstract to be considered for presentation.

**TOPICS FOR RESEARCH SUBMISSIONS:**
Research submissions on the following topics are considered:
- Clinical Outcomes Studies
- Cost Studies
- Patient-Reported Outcomes
- Health Care Use and Policy Studies
- Methods and Concepts

**QUALITY OF STUDY CRITERIA (FOR RESEARCH STUDY ABSTRACTS):**
- Note: For studies involving data collection or analysis, the abstract will be REJECTED if RESULTS are NOT included.
  1. Research design is appropriate and transparent.
  2. Data sources are appropriate and transparent.
  3. Data analyses are appropriate and transparent.
  4. RESULTS ARE INCLUDED and are transparent and comprehensible.
  5. Conclusions are consistent with the results.

**QUALITY OF METHOD OR CONCEPT (FOR METHODS AND CONCEPTS ABSTRACTS):**
- Approach to method and/or concept is apparent.
- Approach represents advancement or is innovative.
- Practical implications/recommendations provided.
- Papers do NOT need to be organized; Objectives: Methods: Results: Conclusions:

**QUALITY OF THE ABSTRACT PRESENTATION CRITERIA:**
1. Objectives/research questions are clearly stated and objectives are addressed.
2. Factual information is kept separate from interpretations or implications/unbiased presentation.
3. Implications/results, as presented, are easy to understand.

**IMPACT FACTOR AND PUBLIC AWARENESS:**
- IMPACT FACTOR: The reviewer will rate the abstract on a scale of 1-5 (1=low impact; 5=very high impact) if the study results described in the abstract will have an impact on health care decisions by health care decision makers and/or patients.
- PUBLIC AWARENESS: The reviewer will indicate (yes, no, or no comment) whether the results of this study will contribute to the health care improvement of society and the public should be made aware of the study results reported in this abstract.

**RESEARCH ABSTRACT EXAMPLE:**

60-MONTH DATA FROM IRIS USED TO UPDATE ESTIMATES OF SURVIVAL AND COST-EFFECTIVENESS OF FIRST-LINE IMATINIB IN PATIENTS WITH CHRONIC PHASE CHRONIC MYELOID LEUKEMIA

Reed SD, Anstrom KJ, Li Y, Schulman KA
Duke Clinical Research Institute, Durham, NC, USA

OBJECTIVES: With 60 months of follow-up data now available from the IRIS trial, we updated our previous cost-effectiveness analysis of first-line imatinib versus interferon-
a plus cytarabine (IFN) in newly diagnosed patients with chronic myeloid leukemia in the chronic phase that was originally based on a median of 19 months of follow-up.

METHODS: We used the empirical 60-month data from IRIS for patients randomized to imatinib to calibrate the survival curves generated with the cost-effectiveness model. Due to the high rate of crossover among patients randomized to IFN in IRIS, we relied on historical data to model survival estimates for patients treated with IFN. We updated costs to 2006 values and applied two sets of costs to imatinib and IFN: average wholesale prices (AWP) and wholesale acquisition costs (WAC). RESULTS: Survival at 5 years for patients randomized to imatinib was better than predicted with our original model (89.4% vs. 83.2%). After model calibration, we estimated remaining life expectancy for first-line imatinib patients to be 19.1 years, an increase of 3.8 years over the original model. Remaining quality-adjusted life-years (QALYs) were estimated at 15.2, an increase of 3.1 QALYs. Estimates for patients randomized to IFN were maintained at 9.1 years and 6.3 QALYs. With AWP, ICERS ranged from $40,300 to $57,100 per QALY when applying less and more conservative assumptions about the duration of first- and second-line treatment with imatinib and IFN. With WACs, ICERS ranged from $33,500 to $46,100 per QALY. CONCLUSIONS: Although our analysis revealed that our initial survival estimates were conservative, the updated ICERS were relatively consistent with our original estimate of $43,300 per QALY. Periodically updating cost-effectiveness analyses should be a routine practice in cases where ongoing survival data are collected. Even with 5 years of data, most of the expected survival benefit has yet to be observed.
GENERAL INFORMATION
- Contributed Workshops are designed to share novel and innovative experiences in either the conduct of pharmacoeconomics and outcomes research studies or the interpretation and use of pharmacoeconomics and outcomes information in health care policy development.
- Workshop submissions must be organized as follows: Workshop Purpose, Workshop Description
- Accepted workshop submissions are published AS SUBMITTED in the Meeting Program and Schedule of Events.

TOPICS FOR WORKSHOP PROPOSALS:
Workshop submissions are accepted on the following topics:
- Clinical Study Methodology
- Cost Study Methodology
- Patient-Reported Outcomes Study Methodology
- Preference-Based Studies Methodology Including Utility Studies
- Formulary Development Research
- Health Care Policy Development Using Outcomes Research
- Risk assessment/risk management
- Compliance/Persistence
- Patient Registry Development
- Use of Real World Data

CRITERIA FOR EVALUATION OF CONTRIBUTED WORKSHOPS:
ISPOR recognizes that a primary purpose of workshops is to allow the presenter(s) to demonstrate their competence in a topic or subject area. However, attendees expect a scientific discourse, so it is important that these contributed workshops are not used as a marketing platform for the presenter’s company products or services.

Workshop acceptance is based on the quality of the proposal and the topic for discussion. Specific criteria for acceptance are:
- The workshop purpose(s) are clearly stated.
- The purpose(s) can be achieved in the 60 minutes allotted for this workshop.
- The information / issue(s) presented are novel or innovative.
- The workshop presentation should contain original scientific content and not just report on the routine use of a single instrument of tool.
- Examples should be drawn from a number of sources and not just the presenter(s) own slides.
- Preference is given to proposals that involve presenters from more than one organization and more than one sector.
- The information / issue(s) presented are valuable to the pharmacoeconomic and outcomes researcher or the health care decision-maker.
- There is an audience interactive element in the workshop.
- The workshop does NOT appear to be advertising the presenter’s company’s services or products.

WORKSHOP PROPOSAL EXAMPLE:

DEVELOPMENT AND VALIDATION OF CONCEPTUAL MODELS, CONCEPTUAL FRAMEWORKS AND ENDPOINT MODELS FOR PRO RESEARCH

DISCUSSION LEADERS: Diane Wild MSc, Director, Oxford Outcomes Ltd, Oxford, UK; Christina Donatti LLB, MSc, PsyD, PhD-student, General Practitioner, University of Southern Denmark, Research Unit of General Practice, Odense, Denmark; Palie Mark Christensen PhD, Senior Outcomes Researcher, Oxford Outcomes Ltd, Oxford, UK; Asha Hareendran PhD, Manager, Outcomes Research, Pfizer Ltd, Sandwich, UK; Annabel Nixon PhD, Senior Outcomes Researcher, Oxford Outcomes Ltd, Oxford, UK

Workshop Purpose: The purpose of this workshop is to understand and clarify the role of conceptual models, conceptual frameworks and endpoint models in light of the recent draft FDA guidance document.

Workshop Description: Conceptual models, conceptual frameworks and endpoint models are essential research tools used by patient reported outcome (PRO) researchers. However, there is considerable lack of agreement regarding their definition, development and validation approach, and utilisation. The purpose of this workshop is to understand and clarify the role of each tool, in light of the recent draft FDA guidance document. Discussions will examine the perspective of the FDA as well as the clinical research perspective and implications for the development and validation of PRO tools to support product label claims. Specifically, the following issues will be addressed for conceptual models, conceptual frameworks and endpoint models:
- Clarification and description of purpose
- Establish the current FDA/EMEA position
- Quantitative and qualitative methodologies for development and validation
- Timing issues in the context of clinical research programs
- Utilisation of each as complementary research tools. Examples will be drawn from the presenters’ own research experiences as well as from the published literature. The implications for clinical and clinical trial research will be discussed. Audience participation will be encouraged through active discussion and the workshop will also include an interactive team-based exercise focused on clarifying the role and design of conceptual models, conceptual frameworks and endpoint models. This workshop will be of interest to PRO/health-related quality of life (HRQL) researchers and those involved in clinical research including drug development.

CONTRIBUTED ISSUE PANEL PROPOSAL INFORMATION

GENERAL INFORMATION
Contributed Issues Panels are designed to stimulate real debate on new or controversial issues in health economic/pharmacoeconomic and outcomes research or use of outcomes research in health care decision-making.

An Issue Panel is composed of a moderator and 2 to 3 panelists.
To assure lively debate, panelists and/or moderator should be from different institutions and/or work environments representing different perspectives to the debate.
Panelists should present distinct views about the topic.
Panelist submissions must be organized as follows:
- TITLE: Full title of your Issue Panel (showing the debate issue in the title is recommended)
- MODERATOR AND/OR CONTACT PERSON: Name, degrees, position, and full contact information for the Moderator of the Issue Panel

ISSUE PANEL EXAMPLE ON THE FOLLOWING PAGE

CRITERIA FOR EVALUATION OF THE CONTRIBUTED ISSUE PANEL
Is the issue clearly defined?
Is more than one perspective identified?
Is the background information (included in the overview) clear and concise?
Is there time allotted for audience discussion and debate?
ISPOR 13th Annual International Meeting
Sheraton Centre Toronto, Toronto, Ontario, Canada, May 3-7, 2008

SUBMISSION INSTRUCTIONS, CONTINUED

ISSUE PANEL PROPOSAL EXAMPLE:

SHOULD THERE BE DIFFERENT CRITERIA FOR ASSESSING ORPHAN DRUGS?

Moderator: Peter J. Neumann ScD, Professor, Tufts University School of Medicine, Boston, MA, USA
Panelists: David Wilson MA, Director Health Economics, Genzyme Corporation, Cambridge, MA, USA; Mike F. Drummond PhD, Professor, University of York, York, Heslington, UK; Peter Littlejohns MD, Clinical and Public Health Director, National Institute for Health and Clinical Excellence, London, UK

ISSUE: Should there be different criteria for assessing orphan drugs?

OVERVIEW: People with rare diseases have historically been underserved by commercial drug development. This has led several countries to enact legislation to encourage the development of drugs for rare diseases (commonly known as ‘orphan drugs’). Whilst this has been successful in producing more orphan drugs, these products typically have high incremental cost-effectiveness ratios, because the development costs need to be recouped from a smaller market. In addition, the small patient population means that it is often difficult to conduct traditional clinical trials. This adds to the uncertainty surrounding the cost-effectiveness estimate. Therefore, in applying the standard methods of health technology assessment, such drugs are unlikely to prove cost-effective. This poses a dilemma. Namely, despite encouraging the development of these products, should patient access be denied? Alternatively, should the criteria of assessment be changed (i.e., the analytic methods, or the threshold of societal willingness-to-pay) so that funding can be made available?

CONTRIBUTED CASE STUDY ABSTRACT INFORMATION

GENERAL INFORMATION
- Case Study abstracts from health care decision makers are designed to describe situations where organizations attempted to integrate cost and outcome information into their processes and procedures for pharmaceuticals, devices, or medical procedures. ISPOR encourages submissions describing successes, works in progress, or failures in this domain.
- The case study should include issues involved in the process or decision including the usefulness or non-usefulness of the outcomes research information, and recommendations, if appropriate, on the outcomes research information regarding information transparency, completeness of data, format or presentation of information.
- The primary author of a case study abstract must be a health care decision-maker.

POSSIBLE TOPICS FOR CASE STUDY ABSTRACTS

Topics for case study abstracts may include but are not limited to:
- Attempts to introduce cost or cost-effectiveness information into formulary decision making processes of Pharmacy and Therapeutics committees.
- Pay for performance programs that focus on patient oriented outcomes or reducing health care expenditures.
- Initiatives to measure patient reported outcomes as part of clinical quality improvement initiatives.
- Purchasing or contracting negotiations with manufacturers that involve cost-effectiveness or outcomes measures as opposed to product prices.

CASE STUDY ABSTRACT EXAMPLE:

IMPLEMENTATION AND EVALUATION OF AN EVIDENCE-BASED CONTINUUM FOR HIP AND KNEE REPLACEMENTS IN ALBERTA

Wasylik T1, Layhey M1, McBain D1, Frank C1, Gooch K1, Hibbert J2
1Calgary Health Region, Calgary, AB, Canada, 2Capital Health, Edmonton, AB, Canada

Organization: Alberta Province [A new evidence-based continuum (referral to recovery) for hip and knee replacements was piloted in Alberta within the Calgary Health Region, the David Thompson Health Region and Capital Health Region.]

Problem or Issue Addressed: Redesigning an evidence based continuum for hip and knee replacements. Bone and joint related conditions place a heavy burden on health care systems and can significantly impact patient quality of life. As the population ages and new technologies are emerging, there is profound concern about the sustainability of care for patients with bone and joint related conditions. The demand for hip and knee replacements is increasing due to changes in patient demographics (e.g., obesity) and an aging population. This increasing demand coupled with the current burden on health care resources and increasingly long wait times emphasized the urgency for health reform.

Goals: The three participating regional health authorities (Calgary Health, Calgary Health Region, David Thompson Health Region) in conjunction with the Alberta Bone and Joint Health Institute and other partners designed and tested a new evidence based continuum of care for hip and knee replacements. The goals of this new continuum included significant improvement in the areas of access, quality and cost. This newly designed continuum coordinated the patient’s journey from referral to recovery. Standardized clinical paths, patient education and accountability, clinic care teams, and dedicated operating rooms and inpatient units were examples of how the continuum was redesigned. To evaluate the new continuum, a randomized controlled evaluation was applied to ensure robust results that would increase the confidence of decision makers regarding the continuation of the new model.

Outcomes items used in the decision: Evaluation outcomes for 1568 patients were analysed that included appropriateness, efficiency, effectiveness, cost and cost-effectiveness, safety, and access. The analyses compared the outcomes of the new continuum to the standard current care. Due to the randomized controlled designed approach, the analyses were not confounded by patient or regional biases.

Implementation Strategy: Within each region a new pre- and post-operative clinic along with dedicated operating rooms and inpatient beds were established to implement and test the new continuum. To avoid the risk of contamination, these newly established facilities were physically separated from the current way. The new care path included clinical pathways that were developed and implemented to train the health care providers to adhere to the new continuum. Agreed by all pilot partners, data were systematically collected, evaluated, and used to compare the current system to the new continuum to enhance appropriate decision making about potential province-wide adaptation of the new model. This evaluation required ethical approval and individual patient consent.

Results: Results from the randomized control trial demonstrated that the new model was significantly more efficient, more effective, and more cost effective (on a cost per patient basis) than the current system. No difference in safety outcomes at three months post-surgery were seen between intervention and control patient groups. Results also highlighted implementation challenges with a change project of this scale particularly as this relates to changes in the behaviour of patients and of providers across the continuum of care.

Lessons Learned: Through the development and implementation of the new continuum, we learned that: 1) advancement of a provincial approach required inclusion of all partners involved in the delivery of care (e.g., physicians, health care providers, decision makers, government), and 2) evidence was not only key to designing a new continuum, but also required as proof of concept and ongoing system monitoring and improvement.
The first portion of this course will provide an overview of the concepts of discrete event simulation. The focus will be on the use of these simulation models to address pharmacoeconomic (and device-related) problems. This course is suitable for those with little or no experience with pharmacoeconomics.

## REAL WORLD DATA METHODS

### Retrospective Database Analysis - Econometric Methods

**Course Description:** Large administrative claims databases provide a unique opportunity to examine retrospectively the effects of drug use on clinical and economic outcomes in "real world" settings. This course will cover a discussion of the ISPOR Checklist for Retrospective Database Studies - Report of the ISPOR Task Force on Retrospective Databases and selected topics related to estimators and sampling distributions, properties of sampling distributions (bias, efficiency, mean square error), and ordinary least squares (OLS) regression. This course will assume participants have knowledge of statistical methods through OLS regression and experience in the analysis of administrative claims databases.

### Bayesian Analysis - Overview and Applications

**Course Description:** The first portion of this course will provide an overview of the Bayesian approach and its applications to health economics and outcomes research. The second portion will focus on the Bayesian "informative prior." Several example vignettes of how a Bayesian analysis can be used within outcomes modeling problems will be presented. Participants should be prepared to use their personal laptops. This course is for those with limited understanding of Bayesian statistical concepts.

## SATURDAY, MAY 3, 2008 (Morning Courses) 8:00AM-12:00PM

### Elements of Pharmaceutical/Biotech Pricing I - Introduction

**Course Description:** This course will give participants a basic understanding of the key terminology and issues involved in pharmaceutical pricing decisions. It will cover the tools to build and document product value, the role of pharmacoeconomics and the differences in payment systems that help to shape pricing decisions. This course is designed for those with limited experience in the area of pharmaceutical pricing.

### Discrete Event Simulation for Economic Analyses

**Course Description:** This course will provide a basic understanding of the key concepts of discrete event simulation. The focus will be on the use of these simulation models to address pharmacoeconomic (and device-related) problems. This course is designed for those with some experience with modeling.

## PHARMACOECONOMIC / ECONOMIC METHODS

### Cost-Effectiveness Analysis alongside Clinical Trials

**Course Description:** This course will present the design, conduct, and reporting of cost-effectiveness analyses alongside clinical trials based on, in part, the Good Research Practices for Cost-Effectiveness Analysis alongside Clinical Trials: The ISPOR RCT-CEA Task Force Report. Analyses guided by an analysis plan and hypotheses, an incremental analysis using an intention to treat approach, characterization of uncertainty, and standards for reporting results will be presented. This course is at an introductory/intermediate level. Familiarity with economic evaluations is helpful.

### Financial Impact / Cost of Illness

**Course Description:** This course will present the design, conduct, and reporting of cost-effectiveness analyses alongside clinical trials based on, in part, the Good Research Practices for Cost-Effectiveness Analysis alongside Clinical Trials: The ISPOR RCT-CEA Task Force Report. Analyses guided by an analysis plan and hypotheses, an incremental analysis using an intention to treat approach, characterization of uncertainty, and standards for reporting results will be presented. This course is at an introductory/intermediate level. Familiarity with economic evaluations is helpful.

### Quality of Life / Patient-Reported Outcomes Methods

**Course Description:** This course will outline the concerns about bias and explain the methods for causal inference in observational studies, where researchers have no control over the treatment assignment. We will explain how propensity scores can be used to reduce bias. Confounding and the pros and cons of standard adjustment and propensity scoring methodology will be discussed. We will also elaborate on risk adjustment models. This course is designed for those with little experience with this methodology but some knowledge of observational databases.
**Short Courses**

**MODELING METHODS**

**Bayesian Analysis: Advanced**
**Course Description:** In this advanced Bayesian applications course, we focus on the use of Markov Chain Monte Carlo methods in conducting policy-relevant outcomes research. Participants will engage in hands-on exercises and address certain methodological issues. The course will conclude with a discussion on the present and future role of Bayesian methods in policy-making. Participants should bring their own laptops, with the latest, unrestricted version of WinBUGS pre-installed. This course is a follow-up to the course: Bayesian Analysis—Overview and Applications.

**Modeling: Design and Structure of a Model**
**Course Description:** This course will include a review of Markov models, discrete event models, and other modeling techniques including a discussion of the ISPOR Principles of Good Practice for Decision Analytic Modeling in Health Care Evaluations. Using a series of related examples, the course will carefully review the practical steps involved in developing and using these kinds of models. This intermediate course requires basic understanding of decision analysis.

**QUALITY OF LIFE / PATIENT-REPORTED OUTCOMES / PREFERENCE-BASED METHODS**

**Patient-Reported Outcomes - Item Response Theory**
**Course Description:** Item response theory (IRT) models the relationship between a person’s response to a survey and their standing on a health construct, allowing instrument developers to develop reliable and efficient quality of life measures. Applications of IRT have increased considerably because of its utility for instrument development and evaluation, assessment of measurement equivalence, instrument linking, and computerized adaptive testing. This introductory workshop will discuss the basics of IRT models and applications to improve health outcomes measurement. This introductory course is designed for those with little to no experience with IRT.

**USE OF PHARMACOECONOMICS / ECONOMIC / OUTCOMES RESEARCH INFORMATION**

**Case Studies in Pharmaceutical/Biotech Pricing II - Advanced**
**Course Description:** Case studies will be employed to lead participants through the key steps of new product pricing, with a focus on the need to thoroughly analyze the business environment and its constraints and opportunities and the need to closely integrate the pricing, reimbursement and pharmacoeconomic strategy for the new product with the clinical development and marketing strategies. This course is for individuals who have completed Elements of Pharmaceutical Pricing I - Introduction or are familiar with both the key determinants of pharmaceutical pricing and the main international health systems.

**PHARMACOECONOMIC / ECONOMIC METHODS**

**Statistical Considerations in Economic Evaluations**
**Course Description:** The adoption and diffusion of new medical treatments depend increasingly on robust analysis of costs and cost-effectiveness. During this course, the following statistical considerations in economic evaluations will be discussed: affect of distributional assumptions, analyzing univariate and multivariable analysis data, analyzing censored data, sample size and power calculations, sampling uncertainty, point estimates for variables, net monetary benefit, and confidence intervals for cost-effectiveness ratios. Participants should have some knowledge of basic economic evaluations and statistics.

**SUNDAY, MAY 4, 2008 (Afternoon Courses) 1:00PM-5:00PM**

**PHARMACOECONOMIC / ECONOMIC METHODS**

**Applications of Statistical Considerations in Health Economic Evaluations**
**Course Description:** This course will provide applications of statistical considerations in economic analysis. Specific exercises will be conducted to illustrate the affect of distributional assumptions, univariate and multivariable analysis of costs, the effect of sample size and power calculations on economic evaluations, and point estimates for cost-effectiveness ratios. Participants who wish to have hands-on experience are encouraged to bring their laptops. The course, Statistical Consideration in Economic Evaluations, is a strong prerequisite for this course.

**REAL WORLD DATA METHODS**

**Patient Registries**
**Course Description:** This course provides an overview of patient registries and their applications in identifying ‘real world’ clinical, safety, and patient-perspective issues. The pros and cons of registry data and how it can support health economics outcomes research initiatives and decision-making will be addressed. AHRO’s Registries for Evaluating Patient Outcomes: A User’s Guide will be discussed. This course is designed for those with little experience with patient registries.

**QUALITY OF LIFE / PATIENT-REPORTED OUTCOMES / PREFERENCE-BASED METHODS**

**Utility Measures**
**Course Description:** Course participants will learn the conceptual and empirical features of various health-utility measures and their relative advantages for different health care decisions. Newer methods allow analysts to estimate “super QALY” values using time or other non-monetary tradeoffs that do not require the restrictive assumptions of conventional cardinal-utility methods. The uses of utility assessment involving individual decisions versus population resource allocations will be compared. This course is designed for those with some experience with psychometric measures.

**OUTCOMES RESEARCH**

**Outcomes Research for Medical Devices & Diagnostics**
**Course Description:** This course will provide an overview of outcomes research practices that are specifically tailored for the fast-paced medical device and diagnostics technology environment and address related issues. Outcomes research for medical devices and diagnostics will be differentiated from other health care interventions such as drugs. The evidence hierarchy for medical devices and diagnostic procedures will be discussed. This course is designed for those with little experience with outcomes research for these technologies.

**USE OF PHARMACOECONOMICS / ECONOMIC / OUTCOMES RESEARCH INFORMATION**

**Introduction to Risk/Benefit Management in Health Care**
**Course Description:** This course will provide an overview of risk/benefit management for pharmaceuticals and devices. The risk/benefit assessment process will be described in regards to stage to product development, from pre-marketing through post-marketing. Risk mitigation includes the various strategies employed by manufacturers, regulators, and health care providers, with an emphasis on international differences in risk mitigation and decision making. Risk/benefit communication processes will be described, focusing upon how decisions regarding risks and benefits of pharmaceuticals and devices are communicated to health care providers and the public. This includes direct mailing, direct-to-consumer marketing, and labeling. Real-world exercises will allow participants to discuss key topics and propose implementation strategies for risk management. This course is designed for those with a basic understanding of pharmacoepidemiology principles.

**MODELING METHODS**

**Advanced Decision Modeling for Health Economic Evaluations**
**Course Description:** During this course, the key aspects and new developments of decision modeling for economic analysis will be considered. How models can be made probabilistic to capture parameter uncertainty (including rationale, choosing parameter distributions, and types of uncertainty) will be covered. How to analyze and present the results of probabilistic models will be presented. The course will focus on probabilistic decision modeling will be interpreted and how decision should be made (including decisions with uncertainty and expected value of perfect information [EVIPI]), will be presented. Specific examples including Excel programming will be used to illustrate concepts. Participants should have a basic understanding of decision analysis. The course, Modeling: Design and Structure of a Model, is a strong prerequisite for this course.
Preliminary Program

Vive la Différence - Enhancing/Expanding Outcomes Research One Country at a Time

MONDAY, MAY 5, 2008

8:00AM-8:30AM WELCOME & INTRODUCTION
Adrian Levy PhD, Director, Oxford Outcomes Ltd, Vancouver, BC, Canada and C. Daniel Mullins PhD, Professor and Chair, Pharmaceutical Health Services Research Department, University of Maryland School of Pharmacy, Baltimore, MD, USA

8:30AM-9:45AM FIRST PLENARY SESSION: New Evidence on Evidence-Based Technology Assessment in the USA vs. Canada
The requirement for evidence when performing technology assessments is viewed by some as a logical process for making decisions and by others as an impossible hurdle and a moving target. Technology assessment occurs quite differently across public and private payers in Canada and the United States, yet all agree that credible evidence is needed for technology assessment and adoption. Panelists representing public and private payers will discuss how they currently assess evidence and conduct technology assessments and how this may change in the future.

9:45AM-10:15AM BREAK, EXHIBITS & CONTRIBUTED POSTER PRESENTATIONS VIEWING - SESSION I

10:15AM-11:15AM CONTRIBUTED PODIUM PRESENTATIONS - SESSION I
Research studies on the following topics may be presented: Cardiovascular Diseases, Respiratory Disorders, Cancer, Infections

11:15AM-11:30AM BREAK

11:30AM-12:30PM LUNCH, EXHIBITS & CONTRIBUTED POSTER PRESENTATIONS VIEWING - SESSION I

12:30PM-2:00PM CONTRIBUTED PODIUM PRESENTATIONS - SESSION II
Research studies on the following topics may be presented: Health Care Reimbursement, Health Care Costs, Health Care Modeling, Screening

2:00PM-3:00PM CONTRIBUTED PODIUM PRESENTATIONS - SESSION II
Research studies on the following topics may be presented: Health Care Reimbursement, Health Care Costs, Health Care Modeling, Screening

3:15PM-4:15PM ISPOR FORUMS
ISPOR STUDENT FORUM, ISPOR SPECIAL INTEREST GROUP FORUMS, ISPOR TASK FORCE FORUMS, ISPOR COUNCIL FORUMS

4:15PM-5:00PM BREAK, EXHIBITS & CONTRIBUTED POSTER PRESENTATIONS VIEWING - SESSION I

4:30PM-5:00PM ISPOR ANNUAL BUSINESS MEETING

5:00PM-6:00PM CONTRIBUTED PODIUM PRESENTATIONS - SESSION III
Research studies on the following topics may be presented: Prescribing Studies, Adherence/Compliance, Pharmacoepidemiology, Outcomes and Preferences

6:00PM-7:00PM AUTHOR PRESENTATION HOUR

6:00PM-8:00PM EXHIBITORS' OPEN HOUSE RECEPTION & CONTRIBUTED POSTER PRESENTATION - SESSION I

TUESDAY, MAY 6, 2008

8:00AM-9:00AM CONTRIBUTED PODIUM PRESENTATIONS - SESSION IV
Research studies on the following topics may be presented: Diabetes, Mental Health, Neurological Disorders, Health Policy Evaluation

9:15AM-9:45AM ISPOR AWARDS PRESENTATION

9:45AM-10:00AM INCOMING PRESIDENTIAL ADDRESS
Chris L. Pashos PhD, Vice President and Executive Director of HERQuLES, Abt Associates - HERQuLES, Lexington, MA, USA

10:00AM-11:00AM SECOND PLENARY SESSION: Drug Safety and Risk-Benefit Decision-Making
Both delayed market entry of life-saving therapies and withdrawals of products from the market underscore the need to determine risk-benefit of a new technology early and often in a product's life cycle. Interest in developing single risk-benefit metrics is reappearing but will these advances lead to improved decision-making? This session will explore how regulators and payers determine the risk-benefit tradeoffs and act upon that information.

11:00AM-11:30AM BREAK, EXHIBITS, CONTRIBUTED POSTER PRESENTATIONS VIEWING - SESSION II

11:30AM-12:30PM ISPOR FORUMS: ISPOR COUNCIL FORUMS, ISPOR SPECIAL INTEREST GROUP FORUMS, ISPOR TASK FORCE FORUMS

12:30PM-2:00PM LUNCH, EXHIBITS, CONTRIBUTED POSTER PRESENTATIONS VIEWING - SESSION II

2:00PM-3:00PM ISSUE PANEL - SESSION II

3:00PM-3:30PM BREAK, EXHIBITS, CONTRIBUTED POSTER PRESENTATIONS VIEWING - SESSION II

3:30PM-5:00PM THIRD PLENARY SESSION: Patient Reported Outcomes: An Objective Assessment
Patient reported outcomes (PROs) are sometimes viewed as inherently subjective because they are derived from patients. There are objective ways to gather and analyze PROs, which must be explored amidst the mounting evidence of international and cultural differences in health-related quality of life that reinforce the subjectivity of responses. This session will review the FDA Guidance on PROs and recommendations from the ISPOR Task Force and explore improvements in methodology and application of PROs.

5:00PM-5:15PM ISPOR CONTRIBUTED RESEARCH AWARDS

5:15PM-6:15PM AUTHOR PRESENTATION HOUR

5:15PM-7:00PM EXHIBITORS' WINE & CHEESE RECEPTION & CONTRIBUTED POSTER PRESENTATIONS VIEWING - SESSION II

7:30PM-11:00PM ISPOR SOCIAL EVENT!!!

WEDNESDAY, MAY 7, 2008

8:00AM-9:00AM CONTRIBUTED WORKSHOPS - SESSION I

9:15AM-10:15AM CONTRIBUTED WORKSHOPS - SESSION II

10:30AM-11:30AM CONTRIBUTED WORKSHOPS - SESSION III

Abstract Submission Deadline: January 7, 2008 / Early Registration Deadline: April 1, 2008
ISPOR 13th Annual International Meeting
Sheraton Centre Toronto, Toronto, Ontario, Canada, May 3-7, 2008

ISPOR Short Course Registration

SATURDAY, MAY 3, 2008
ALL DAY SESSIONS 8:00 AM - 5:00 PM
Pharmacoeconomics for Decision-Makers
Retrospective Database Analysis - Econometric Methods
Bayesian Analysis - Overview and Applications
MORNING SESSIONS 8:00 AM - 12:00 PM
Elements of Pharmaceutical/Biotech Pricing I - Introduction
Discrete Event Simulation for Economic Analyses
Cost-Effectiveness Analysis alongside Clinical Trials
AFTERNOON SESSIONS 1:00 PM - 5:00 PM
Financial Impact / Cost of Illness
Finding and Extracting Cost Data
Advanced Quantitative Methods for Quality of Life / Patient-Reported Outcomes
Instruments Variables in Addressing Selection Bias

SUNDAY, MAY 4, 2008
MORNING SESSIONS 8:00 AM - 12:00 PM
Applications in Using Large Databases
Propensity Scores and Comorbidity Risk Adjustment
Bayesian Analysis: Advanced
Modeling: Design and Structure of a Model
Patient-Reported Outcomes - Item Response Theory
Case Studies in Pharmaceutical/Biotech Pricing II - Advanced
Statistical Considerations in Economic Evaluations
AFTERNOON SESSIONS 1:00 PM - 5:00 PM
Applications of Statistical Consideration in Health Economic Evaluations
Patient Registries
Utility Measures
Outcomes Research for Medical Devices and Diagnostics
Introduction to Risk/Benefit Management in Health Care
Advanced Decision Modeling for Health Economic Evaluations

HALF DAY SHORT COURSE FEES
Registration Before April 1, 2008: REGULAR FEE: US$150 C$160 / STUDENT FEE: US$75 C$80
Registration After April 1, 2008: REGULAR FEE: US$200 C$214 / STUDENT FEE: US$100 C$107

FULL DAY SHORT COURSE FEES
Registration Before April 1, 2008: REGULAR FEE: US$300 C$321 / STUDENT FEE: US$150 C$160
Registration After April 1, 2008: REGULAR FEE: US$400 C$428 / STUDENT FEE: US$200 C$214

ISPOR Meeting Registration

Standard
Registration Before April 1, 2008
REGULAR FEE: US$600 C$642
Registration After April 1, 2008
REGULAR FEE: US$700 C$749
Clinical Practitioners (Clinical Practice, Hospital)
Registration Before April 1, 2008
REGULAR FEE: US$450 C$481
Registration After April 1, 2008
REGULAR FEE: US$550 C$588
Full-Time Government and Academia
Registration Before April 1, 2008
REGULAR FEE: US$300 C$321
Registration After April 1, 2008
REGULAR FEE: US$400 C$428

ISPOR Social Event: Tuesday, May 6
Reg Fee: US$50 C$55 / Student Reg Fee: US$35 C$37

ISPOR Member Non-Member*

Full-Time Students
Registration Before April 1, 2008
REGULAR FEE: US$100 C$107
Registration After April 1, 2008
REGULAR FEE: US$150 C$160
One Day Registration (per day)**
May 5 May 6 May 7
REGULAR FEE: US$350 C$374
Continuing Education Accreditation
REGULAR FEE: US$50 C$53

ISPOR Social Event
REGULAR FEE: US$550 C$585
Student Reg Fee: US$35 C$37

Registration Fees

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Cancellation Details: Cancellation fee before April 1, 2008 is US $100. No refunds given after April 1, 2008.

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