ISPOR 17th Annual International Meeting
June 2-6, 2012
Washington Hilton
Washington, DC, USA

SHORT COURSE PROGRAM
**Course Description:** This course is designed to teach clinicians and new researchers how to incorporate pharmacoeconomics into study design and data analysis. Participants will learn how to collect and calculate the costs of different alternatives, determine the economic impact of clinical outcomes and how to identify, track and assign costs to different types of health care resources used. The development of economic protocols and data collection sheets will be discussed. Different pharmacoeconomic models and techniques will be demonstrated and practiced in lectures and case studies. These include: cost-minimization; cost-of-illness; cost-effectiveness; cost-benefit; and cost-utility analysis. Decision analysis, sensitivity analysis and discounting will all be demonstrated and practiced. Participants will also learn to compare and evaluate interventions such as drugs, devices and clinical services.

**Level:** Introductory. This course is suitable for those with little or no experience with pharmacoeconomics.

---

**Course Description:** The first part of this course is designed to provide an overview of the Bayesian approach and its applications to health economics and outcomes research. The course will cover basic elements of Bayesian statistics, contrasting briefly with classical (frequentist) statistics and introduce available statistical packages. The second part of the course is a “hands-on” workshop where participants will be led through live examples using the free Markov Chain Monte Carlo package WinBUGS. Attendees will have the chance to apply the principles they have learned in part one to challenging data analysis problems, including the use of Bayesian generalized linear models (GLM) to analyze cost and outcomes data.

**Level:** Introductory-Intermediate. This course is designed for those with a limited understanding of Bayesian statistical concepts or for those who want a refresher and more practical experience.

---

**Course Description:** This course is suitable for those with little or no experience with pharmacoeconomics.

---

**Course Description:** The growing number of prospective clinical/economic trials reflects both widespread interest in economic information for new technologies and the regulatory and reimbursement requirements of many countries that now consider evidence of economic value along with clinical efficacy. 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. Trial design, selecting data elements, database design and management, analysis, and reporting of results will be presented. Trials designed to evaluate effectiveness (rather than efficacy), as well as clinical outcome measures will be discussed. How to obtain health resource use and health state utilities directly from study subjects and economic data collection fully integrated into the study will also be discussed. 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.

**Course Description:** Conceptual, methodological, and practical methods for measuring quality of life, health status and other types of health outcomes will be presented. Theoretical frameworks, reliability, validity, responsiveness, methods of
administration, respondent and administrative burdens, and issues of analysis and interpretation will be discussed using examples drawn from specific quality-of-life instruments and their applications. A model of selecting appropriate instruments from the many existing generic and disease-specific instruments will be presented.

**Level:** Introductory. This course is intended for those with little experience with these methodologies.

### USE OF PHARMACOECONOMIC / ECONOMIC / OUTCOMES RESEARCH INFORMATION

**Elements of Pharmacoeconomic/ Biotech Pricing I – Introduction Jefferson West (Concourse Level)**

Faculty: Jack M. Mycka, Global President and CEO, MME LLC, Montclair, NJ, USA; Renato Dellamano, PhD, President, MME Europe & ValueVector (Value Added Business Strategies), Milan, Italy

**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 including issues, information and processes employed (including pricing research); the role of pharmacoeconomics and the differences in payment systems that help to shape pricing decisions will also be discussed. These tools will be further explored through a series of interactive exercises.

**Level:** Introductory. This course is designed for those with little experience in the area of pharmaceutical pricing and covers topics within a global context.

### NEW! The Reader Expectation Approach to Professional Writing Gunston (Terrace Level)

Faculty: George D. Gopen, JD, PhD, Professor, Practice of Rhetoric, Duke University, Durham, NC, USA

**Course Description:** This course approaches written communication from the perspective of the reader. In the professional world, no one cares how hard the writer tried or how much they have improved since last time. To understand the language better we should get to know as fully as possible how readers actually go about the act of interpretation. This short course will introduce participants to five essential components of professional writing, the first steps towards gaining new and better control of written communication.

**Level:** Introductory.

### SATURDAY, JUNE 2, 2012 Afternoon Courses 1:00PM-5:00PM

#### OBSERVATIONAL DATA METHODS

**Patient Registries Gunston (Terrace Level)**

Faculty: Leanne Larson, MHA, Vice-President, Evidence Development, PAREXEL Consulting, USA; Elizabeth Hernberg-Stähl, MSc, Senior Consultant, Founder, Late Phase Solutions Europe AB, Täby, Sweden

**Course Description:** This course is designed to provide 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 compared to other "real world" and clinical trial data collection will be presented. How registry information can be used to support other health economics/ outcomes research initiatives and health care decision making will be addressed. Registry strategy, design, operations and measures of program success will be discussed. In addition, regulatory trends and requirements, including the Agency for Healthcare Research & Quality’s (AHRQ) May 2007 publication: Registries for Evaluating Patient Outcomes: A User’s Guide, will be examined.

**Level:** Introductory. This course is designed for those with little experience with patient registries.

---

**Saturday Afternoon Coffee Break**

Coffee sponsored by Adjility Health
ECONOMIC METHODS
Financial Impact / Cost of Illness Jefferson East (Concourse Level)
Faculty: Josep Mauskopf, PhD, MA, MHA, Vice President, Health Economics, RTI Health Solutions, Research Triangle Park, NC, USA; C. Daniel Mullins, PhD, Professor, Pharmaceutical Health Services Research, University of Maryland School of Pharmacy, Baltimore, MD, USA; Stephanie R. Earnshaw, PhD, MS, Vice President, Health Economics, RTI Health Solutions, Research Triangle Park, NC, USA
Course Description: This course will describe the methods used to estimate the budget impact of a new health care technology. The course will present six basic steps for estimating budget impact: estimating the target population; selecting a time horizon; identifying current and projected treatment mix; estimating current and future drug costs; estimating change in disease-related costs; and estimating and presenting changes in annual budget impact and health outcomes. Both static and dynamic methods for estimating the budget and health impact of adding a new drug to a health plan formulary will be presented. The six steps will be illustrated using actual budget impact models.
Level: Intermediate. This course is designed for those with some experience in pharmacoeconomic analysis.

USE OF PHARMACOECONOMIC/ECONOMIC/OU TCOMES RESEARCH INFORMATION
Case Studies in Pharmaceutical/Biotech Pricing II – Advanced Jefferson West (Concourse Level)
Faculty: Jack M. Mycka, Global President & CEO, MME LLC, Montclair, NJ, USA; Renato Dellamano, PhD, President, MME Europe & ValueVector (Value Added Business Strategies), Milan, Italy
Course Description: Case studies will be employed to lead participants through the key steps of new product pricing, with 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. Practical exercises will allow participants to consolidate the concepts delivered in the "Elements" introductory session and expanded here. Areas covered will include the post-launch issues of reimbursement and pricing maintenance as a part of life-cycle management in a global environment.
Level: Advanced.
*Prerequisite: This course is for individuals who have completed the ISPOR short course, "Elements of Pharmaceutical / Biotech Pricing I – Introduction", or are familiar with both the key determinants of pharmaceutical pricing and the main international health systems.

MODELING METHODS
Modeling: Design and Structure of a Model Lincoln East (Concourse Level)
Faculty: Mark S. Roberts, MD, MPP, Professor, Chair, Department of Health Policy and Management, University of Pittsburgh Graduate School of Public Health, Pittsburgh, PA, USA; Shelby L. Cormán, PharmD, MS, BCPS, Assistant Professor, Department of Pharmacy & Therapeutics, University of Pittsburgh School of Pharmacy, Pittsburgh, PA, USA
Course Description: The purpose of this course is to provide hands-on experience in the development and analysis of a progressively more complex version of an HIV screening model in TreeAge® software. During the session, students will create a simple replication of the decision model presented in: Sanders GD, et al. Cost-effectiveness of screening for HIV in the era of highly active retroviral therapy. N Engl J Med. 352:570-85, 2005. Starting with a simple tree, the model will be extended to a cost-effectiveness analysis, and then extended again to represent the outcomes as Markov processes. Experience in multiple types of sensitivity analysis (one way, multi-way and probabilistic) will be provided. Participants who wish to have hands-on experience must bring their laptops.
Level: Intermediate. Participants should have a basic understanding of decision analysis.
*Prerequisite: Participation in the ISPOR short course "Introduction to Modeling Methods" (or equivalent knowledge) is required.

SUNDAY, JUNE 3, 2012
Morning Courses 8:00AM-12:00PM

MODELING METHODS
Discrete Event Simulation for Economic Analyses – Concepts Gunston (Terrace Level)
Faculty: J. Jaime Caro, MD, MRCGP, FRPCP, FACP, Senior Vice President, Research, United BioSource Corporation, Lexington, MA, USA and Adjunct Professor of Medicine & Epidemiology & Biostatistics, McGill University, Montreal, Canada; Jörgen Möller, MSc Mech Eng, Vice President, Modeling, United BioSource Corporation, Hammersmith, UK and Associate Researcher, Division of Health Economics, Faculty of Medicine, Lund University, Sweden; Denis Getsios, Senior Director, Senior Research Scientist, United BioSource Corporation, Lexington, MA, USA
Course Description: This course will provide a basic understanding of the key concepts of discrete event simulation. Topics to be covered are: how does it work; what are the components; where is it used; for which problems is DES well suited; what are the advantages and disadvantages of DES; PSA as a simple task. The focus will be on the use of these simulation models to address pharmacoeconomic (and device-related) problems.
Level: Introductory. This course is designed for those with some familiarity with modeling.
*Prerequisite: Attendance at the ISPOR short courses, “Introduction to Modeling Methods” and “Modeling: Design and Structure of a Model” (or equivalent knowledge) is recommended.

Sunday Morning Coffee Break
Coffee sponsored by BaseCase Software

Bayesian Analysis – Advanced Fairchild (Terrace Level)
Faculty: Keith R. Abrams, PhD, Professor of Medical Statistics, Department of Health Sciences, University of Leicester, Leicester, UK; Christopher S. Hollenbeak, PhD, Associate Professor, Surgery and Public Health Sciences, Penn State College of Medicine, Hershey, PA, USA; David J. Vanness, PhD, Assistant Professor, University of Wisconsin School of Medicine and Public Health and Visiting Scientist, Health Economics and Science Policy, United BioSource Corporation, Madison, WI, USA
Course Description: This course introduces the use of Bayesian methods in evidence synthesis (including meta-analysis) and allows participants to gain hands-on experience using such modeling techniques within WinBUGS. Methodological issues considered in the course include: fixed and random effects models, choice of prior distributions, subgroups, meta-regression and adjusting for baseline risk, together with indirect and mixed treatment comparisons. Further meta-analysis topics for which a Bayesian approach can be of benefit will also be highlighted. Participants will be expected to be familiar with the use of WinBUGS and will be responsible for bringing a laptop with the latest, unrestricted version of WinBUGS pre-installed [Details at www.mrc-bsu.cam.ac.uk/bugs]. Participants who wish to have hands-on experience must bring their laptops.
Level: Advanced.
*Prerequisite: Previous attendance at the ISPOR short course "Bayesian Analysis – Overview and Applications" – or equivalent knowledge – is required. Basic knowledge of the Bayesian approach and use of WinBUGS will be assumed.
be addressed in order to obtain valid empirical preference estimates. The course will be structured following the good research practice guidelines and discussion being prepared by the ISPOR Good Research Practices for the Application of Conjoint Analysis in Health Task Force. The course will include lectures and interactive group exercises and group discussion.

Level: Intermediate. This course is designed for clinicians, policymakers, researchers, and patient advocates/researchers with some knowledge of conjoint analysis or other stated-preference methods.

Utility Measures Jefferson East (Concourse Level)

Faculty: Andrew Lloyd, DPhil, Vice President (Practice Lead), Patient Reported Outcomes, Oxford Outcomes Ltd., Oxford, UK; Sarah Acaster, MSc, Director, Patient Reported Outcomes, Oxford Outcomes, San Francisco, CA, USA

Course Description: This course is designed to provide an introduction and overview of utility measures to support economic evaluations. The concepts of health-related quality of life and utility will be introduced and discussed in terms of their differences and similarities. We will describe how these data can be combined with survival to estimate quality-adjusted life years. Some issues for debate will be introduced. In the second section we will explore the methods that are used to capture utilities such as standard gamble, time trade off and rating scales. Building on this will be a presentation of the different generic instruments that have been developed for measuring quality of life such as the EQ-5D, Health Utilities Index and SF-36. Estimating utilities from a condition-specific measure will also be discussed. In the third section we will describe approaches that can be used when utility data from trials are not available. The development of mapping functions and other crosswalks will be described from disease-specific measures to generic HRQL measures. The pros and cons of the different main approaches will be discussed. Other approaches to addressing a lack of utility data will also be described including prospective observational studies, systematic reviews, critical appraisal of published values and the valuation of vignette type descriptions of health. In the final section we will describe the requirements and preferences of different reimbursement agencies around the world including UK/Australia/Canada; US agencies; EU markets such as Sweden/Belgium/Netherlands/Germany; Asia and Latin America. The course will be interactive with break-out sessions and group discussion.

Level: Introductory. No prior knowledge of utilities or health-related quality of life is assumed.

OBSERVATIONAL DATA METHODS

Instrumental Variables in Addressing Selection Bias in Observational Studies Monroe (Concourse Level)

Faculty: Benjamin M. Craig, PhD, Assistant Member, Health Outcomes and Behavior, Moffitt Cancer Center and Associate Professor, Department of Economics, University of South Florida, Tampa, FL, USA; Antoine C. El Khoury, PhD, MS, Director, Market Access and Health Economics, Johnson and Johnson, Horsham, PA, USA and Adjunct Assistant Professor, Division of Pharmaceutical Evaluation and Policy, University of Arkansas for Medical Sciences College of Pharmacy, Little Rock, AR, USA; Bradley C. Martin, PhD, RPh, PharmD, Professor, Head, Division of Pharmaceutical Evaluation and Policy, University of Arkansas for Medical Sciences College of Pharmacy, Little Rock, AR, USA

Course Description: In any non-randomized study, selection bias is a potential threat to the validity of conclusions reached. Failure to account for sample selection bias can lead to conclusions about treatment effectiveness or treatment cost that are not really due to the treatment at all, but rather to the unobserved factors that are correlated with both treatment and outcomes. Sample selection models provide a test for the presence of selection bias. These models also provide a correction for selection bias, enabling an investigator to obtain unbiased estimates of treatment effects. This course will discuss the various models and their applications, and in particular will address instrument variables (two-stage least squares, intuition, RCITs), including an overview of examples from the current literature. Participants will benefit from interactive exercises using instrumental variables and sample selection
techniques using STATA. (For those who have STATA loaded on their laptops, you are encouraged to bring your laptop).

**Level: Intermediate.** This course is suitable for those with some knowledge of econometrics.

*Prerequisite: Previous attendance at the ISPOR short course "Introduction to Retrospective Database Analysis" – or equivalent knowledge – is recommended.

## ECONOMIC METHODS

### Statistical Considerations in Health Economic Evaluations

**Jefferson West (Concourse Level)**

**Faculty:** Henry Glick, PhD, Associate Professor of Medicine, Division of Internal Medicine, School of Medicine, University of Pennsylvania, Philadelphia, PA, USA; Jalpa A. Doshi, PhD, Assistant Professor of Medicine, Division of General Internal Medicine and Director, Economic Evaluations Unit, Center for Evidence-Based Practice and Director, Value-Based Insurance Design Initiatives, Center for Health Incentives and Behavioral Economics, University of Pennsylvania, Philadelphia, PA, USA.

**Course Description:** Adoption and diffusion of new medical treatments depend increasingly on analysis of costs and cost-effectiveness. During this course, we discuss design issues for the collection of primary economic data as well as statistical considerations, including the effect of distributional assumptions, univariate and multivariate analyses of data, sample size and power calculations, and estimation of sampling uncertainty. Examples will be provided to illustrate concepts.

**Level: Intermediate.** Participants should have basic knowledge of economic evaluations and statistics.

## SUNDAY, JUNE 3, 2012

### Afternoon Courses 1:00PM-5:00PM

**ECONOMIC METHODS**

### Applications of Statistical Considerations in Health Economic Evaluations

**Jefferson West (Concourse Level)**

**Faculty:** Henry Glick, PhD, Associate Professor of Medicine, Division of Internal Medicine, School of Medicine, University of Pennsylvania, Philadelphia, PA, USA; Jalpa A. Doshi, PhD, Assistant Professor of Medicine, Division of General Internal Medicine and Director, Economic Evaluations Unit, Center for Evidence-Based Practice and Director, Value-Based Insurance Design Initiatives, Center for Health Incentives and Behavioral Economics, University of Pennsylvania, Philadelphia, PA, USA.

**Course Description:** This course will provide applications of statistical considerations in economic analysis. Specific exercises will be conducted to illustrate univariate and multivariate analysis of costs (including the effect of distributional assumptions), sample size and power calculations for cost-effectiveness analysis, and estimation of confidence intervals for cost-effectiveness ratios and net monetary benefits as well as acceptability curves. Participants who wish to have hands-on experience must bring their laptops. Statistical analysis will be done by use of STATA. A trial version of the software will be distributed for those who do not have the software. The text *Economic Evaluation in Clinical Trials* (Oxford: OUP, 2007) is recommended reading for this course.

**Level: Advanced.**

*Prerequisite: Previous attendance at the ISPOR short course "Statistical Considerations in Health Economic Evaluations"*, is required.

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

### Risk-Sharing/Performance-Based Arrangements for Drugs and Other Medical Products

**Lincoln West (Concourse Level)**

**Faculty:** Lou Garrison, PhD, Professor, Pharmaceutical Outcomes Research and Policy Program, Department of Pharmacy, University of Washington, Seattle, WA, USA; Adrian Towe, MA, MPH, Director; Office of

Health Economics, London, UK; Josh Carlson, PhD, Research Assistant Professor, Pharmaceutical Outcomes Research and Policy Program, Department of Pharmacy, University of Washington, Seattle, WA, USA.

**Course Description:** There is significant and growing interest among both the payers and producers of medical products for arrangements that involve a “pay-for-performance” or “risk-sharing” element. These payment schemes involve a plan by which the performance of the product is tracked in a defined patient population over a specified period of time and the level of reimbursement is tied by formula to the outcomes achieved. Although these agreements have an intrinsic appeal, there can be substantial barriers to their implementation. Theory and practice, including incentives and barriers, will be analyzed along with several examples of performance-based schemes from Europe, the United States, and Australia. A hypothetical case study will be used in an interactive session to illustrate a systematic approach to weighing their applicability and feasibility.

**Level: Intermediate.**

*Prerequisite: It will be helpful for individuals taking this course to have completed the ISPOR short course "Elements of Pharmaceutical/Biotech Pricing I – Introduction", or to be familiar with both the key determinants of pharmaceutical pricing and the main international health systems.

### Sunday Afternoon Coffee Break

Coffee sponsored by IHS

**OUTCOMES RESEARCH METHODS**

### Outcomes Research for Medical Devices and Diagnostics

**Monroe (Concourse Level)**

**Faculty:** Seema Sonnad, PhD, Associate Professor & Director, Outcomes Research, Department of Surgery, University of Pennsylvania, Philadelphia, PA, USA; Stacey Ackerman, MSE, PhD, Vice President, Covance Market Access Services, San Diego, CA, USA.

**Course Description:** This course will present outcomes research practices that are specifically tailored for the fast-paced medical device and diagnostics technology environment and address issues related to these health technology assessment methodologies. Outcomes research including clinical outcomes, economic outcomes, and patient-reported outcomes as described in the recent ISPOR publication, *Therapeutic & Diagnostic Device Outcomes Research* (Lawrenceville, NJ: ISPOR, 2011) will be discussed. 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 including “real world” outcomes research information in coverage and reimbursement decisions will be reviewed.

**Level: Introductory.** This course is designed for those with little experience with outcomes research for medical device and diagnostic technologies.

**NEW! Network Meta-analysis for Indirect Treatment Comparison**

**Lincoln East (Concourse Level)**

**Faculty:** Joseph C. Cappelleri, PhD, MSc, MPH, Senior Director, Pfizer Inc., New London, CT, USA; Jeroen P. Jansen, PhD, MSc, Vice President - Health Economics & Outcomes Research, MAPI Consultancy, Boston, MA, USA.

**Course Description:** For several medical questions of interest, many treatment options exist for the same indication. These treatments may be compared against placebo or against each other in clinical trials. Knowing whether one specific treatment is better than placebo or some other specific comparator is only a fragment of the big picture, which should incorporate all available information. Ideally, one would like to know how all the different treatment options rank against each other and how big the differences are in effect size between all the available options. Network meta-analysis offers a quantitative method of integrating all the data from all the available comparisons. Based, in part, on two ISPOR Task Force Reports on Indirect Treatment Comparisons, the fundamentals and concepts of network meta-analysis will be presented, which is especially useful when there’s little or no evidence from direct comparisons. Network
meta-analysis provides an integrated and unified analysis that incorporates all direct and indirect comparative evidence about treatments. Nevertheless, the evaluation of networks also presents special challenges and caveats, which will also be highlighted in this course. The material in this course is motivated by instructive and real examples. Case studies are implemented with the WinBUGS package.

**Level: Intermediate.** This course is of an intermediate level, requiring at least a basic knowledge of meta-analysis and statistics.

*Prerequisite: The ISPOR short course, “Meta-Analysis & Systematic Reviews in Comparative Effectiveness Research” is a prerequisite for this course. Participants must have knowledge of statistical methods.

**OBSERVATIONAL DATA METHODS**

**Propensity Scores and Observational Studies of Treatment Effect Georgetown (Concourse Level)**

Faculty: John D. Seeger, PharmD, DrPH, Assistant Professor of Medicine (HMS) and Adjunct Assistant Professor of Epidemiology (HSPH), Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women’s Hospital/Harvard Medical School, Boston, MA, USA

Course Description: In observational research, issues of bias and confounding relate to study design and analysis in the setting of non-random treatment assignment where compared subjects might differ substantially with respect to comorbidities. No control over the treatment assignment and the lack of balance in the covariates between the treatment and control groups can produce confounded estimates of treatment effect. We will explain how propensity scores can be used to mitigate confounding, through standard observational approaches (restriction, stratification, matching, regression, or weighting). The advantages and disadvantages of standard adjustment relative to propensity score-based methods will be discussed. Details of propensity score methodology (variable selection, use, and diagnostics) will also be discussed. The course will also elaborate briefly on risk adjustment models that collapse predictors of outcomes (disease risk scores such as the Charlson Comorbidity Index, and Chronic Disease Scores) and their use relative to propensity scores.

Level: Intermediate. This course is designed for those with little experience with this methodology but some knowledge of observational databases.

*Prerequisite: Previous attendance at the ISPOR short course "Introduction to Retrospective Database Analysis" – or equivalent knowledge – is recommended.

**PATIENT-REPORTED OUTCOMES / PREFERENCE-BASED METHODS**

**Content Validity of PRO, ClinRO and ObsRO Assessments Fairchild (Terrace Level)**

Faculty: Donald L. Patrick, PhD, MSPH, Professor, University of Washington, Seattle Quality of Life, Seattle, WA, USA; Mona L. Martin, RN, MPA, Executive Director, Health Research Associates, Inc., Seattle, WA, USA; Chad Gwaltney, PhD, Senior Scientist, PRO Consulting, Pittsburgh, PA, USA and Assistant Professor (Research), Department of Community Health, Brown University, Providence, RI, USA; Nancy Kline Leidy, PhD, Senior Vice President, Scientific Affairs, United BioSource Corporation, Bethesda, MD, USA

Course Description: This course will focus on establishing the content validity of patient-reported outcomes (PRO), clinician-reported outcomes (ClinRO) and observer-reported outcomes (ObsRO) assessments that are intended for use as the basis for medical product claims in the US and Europe. The evidences for supporting content validity take into account the recommendations of the FDA Guidance for Industry – Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims and the EMA Reflection Paper on the Regulatory Guidance on the Use of Health-Related Quality of Life (HRQL) Measures in the Evaluation of Medicinal Products. After this course, participants will be able to: define the essential evidences needed for establishing and documenting content validity of assessments planned for use in applications for regulatory approval of desired medical product claims. Examples will be given throughout on each evidence requirement. Participants will take part in several practical exercises that are part of the iterative process for determining and establishing evidence of content validity for instruments. Faculty will also reference the ISPOR Good Research Practices for Evaluating and Documenting Content Validity for the Use of Existing Instruments and Their Modifications PRO Task Force Report.

Level: Advanced. This course assumes attendees have a basic understanding of qualitative interviewing methods and measurement properties of PRO instruments.

**MODELING METHODS**

**Discrete Event Simulation for Economic Analyses – Applications Gunston (Terrace Level)**

Faculty: J Jaime Caro, MDCM, FRCP, FACP, Senior Vice President, Research, United BioSource Corporation, Lexington, MA, USA and Adjunct Professor of Medicine & Epidemiology & Biostatistics, McGill University, Montreal, Canada; Jörgen Möller, MSc Mech Eng, Vice President, Modeling, United BioSource Corporation, Hammersmith, UK and Associate Researcher, Division of Health Economics, Faculty of Medicine, Lund University, Sweden; Denis Getsios, Senior Director, Senior Research Scientist, United BioSource Corporation, Lexington, MA, USA

Course Description: This course is structured around practical discrete event simulation exercises. Topics to be covered are: Components of a DES; How do you build a model? Modeling of processes and resource use; Modeling of variables and decisions. Simple animation will be demonstrated. We will use ARENA to build entry level models. Instructions for downloading training version of Arena will be distributed prior to the course. Participants who wish to have hands-on experience must bring their personal laptops with Arena installed.

Level: Intermediate. This course is designed for those with some understanding of discrete event simulation (equivalent to attendance at the short course "Discrete Event Simulation for Economic Analysis – Concepts") and who wish to have more practical modeling experience.

*Prerequisite: Attendance at the ISPOR short course "Discrete Event Simulation for Economic Analysis – Concepts", or equivalent knowledge, is required.

**Advanced Decision Modeling for Health Economic Evaluations Jefferson East (Concourse Level)**

Faculty: Andrew Briggs, DPhil, MSc, William R Lindsay Chair of Health Economics, Health Economics & Health Technology Assessment, Institute of Health & Wellbeing, University of Glasgow, Glasgow, UK; Mark Sculpher, PhD, MSc, Professor of Health Economics, Centre for Health Economics, University of York, Heslington York, UK

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. How the results of probabilistic decision modeling should be interpreted and how decisions should be made (including decisions with uncertainty, and expected value of perfect information [EVPI]), will be presented. Specific examples including Excel programming will be used to illustrate concepts.

Level: Advanced. Participants should have an understanding of decision analysis.

*Prerequisite: Previous attendance at the ISPOR short course "Modeling: Design and Structure of a Model" – or equivalent knowledge – is required.